Knee joint stiffness and function following Total Knee Arthroplasty

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Declaration

I hereby declare that;

1) This thesis has been composed entirely by myself,
2) The material contained within this thesis is entirely my own work,
3) The material contained within this thesis not been submitted for any other degree or professional qualification.

Signed: [Signature]

[Tedward Lowe]
Abstract

Introduction: Studies show that Total Knee Arthroplasty (TKA) is successful for the majority of patients however some continue to experience some functional limitations and anecdotal evidence indicates that stiffness is a common complaint. Some studies have suggested an association between stiffness and functional limitations however there has been no previous work which has attempted to objectively quantify knee joint stiffness following TKA. The purpose of this study was to pilot and evaluate a method for the quantitative evaluation in joint stiffness in replaced knees, OA knees and healthy controls and to explore whether there is an association between stiffness and functional limitations post-TKA surgery.

Methods: The first part of the study created a biomechanical model of knee stiffness and built a system from which stiffness could be calculated. A torque transducer was used to measure the resistance as the knee was flexed and extended passively and an electrogoniometer concurrently measured the angular displacement. Stiffness was calculated from the slope of the line relating the passive resistive torque and displacement. The torque and joint angle at which stiffness was seen to increase greatly was also noted. The system was bench tested and found to be reliable and valid. Further tests on 6 volunteers found stiffness calculations to have acceptable intra-day reliability.

The second part was conducted on three groups: those with end-stage knee OA (n = 8); those who were 1 year post-TKA (n = 15) and age matched healthy controls (n = 12). Knee range of motion was recorded and participants then completed the WOMAC, the SF-12 and a Visual Analogue Score for stiffness as well as indicating words to describe their stiffness. Four performance based tests – the Timed Up and
Go (TUG), the stair ascent/descent, the 13m walk and a quadriceps strength test were also undertaken. Finally, passive stiffness at the affected knee was measured.

**Results:** 100% of OA, 80% of TKA and 58% of controls reported some stiffness at the knee. The OA group reported significantly higher stiffness than the OA or TKA groups. There was no difference in self-reported stiffness between the TKA and control groups. Of the total number of words used to describe stiffness, 52% related to difficulty with movement, 35% were pain related and 13% related to sensations. No significantly differences were found between groups in the objective stiffness measures. Significant differences were found however in threshold flexion stiffness angles between groups. When this angle was normalised, differences between groups were not significant. No significant differences were found between groups in the threshold stiffness torque. Greater self-reported stiffness was found to be associated with worse self-reported function. A higher flexion stiffness threshold angle was associated with slower timed tests of function but also with better quadriceps muscle strength.

**Conclusions:** The results support anecdotal reports that perceived stiffness is a common complaint following TKA but there was no evidence to show that patients with TKA have greater stiffness than a control group. There was however evidence to show that patients’ were unable to distinguish between sensations of stiffness and other factors such as pain. Self-perceived increased stiffness was associated with worse functional performance. Greater stiffness however was not necessarily negative. Stiffness increases earlier in flexion range were associated with better functional performance. These results suggest that an ideal threshold range for stiffness may exist; above which negative perceptions of the knee result in worse
function but below which, knee laxity and instability may also result in worse function.
Acknowledgements

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Table of Contents

Declaration ......................................................................................................................... ii
Abstract .............................................................................................................................. iii
Acknowledgements .......................................................................................................... vi
Table of Figures ................................................................................................................ xii

1 Introduction ...................................................................................................................... 1

2 Review of the related literature ..................................................................................... 3

2.1 The Aging and Osteoarthritic Knee Joint ................................................................. 3

2.2 Outcomes in Total Knee Arthroplasty ...................................................................... 5

2.2.1 Clinical Outcomes ............................................................................................... 6

2.2.2 Patient reported outcomes .................................................................................. 8

2.2.2.1 Questionnaires .................................................................................................. 9

2.2.2.2 Qualitative research ....................................................................................... 17

2.2.3 Objective measures of outcome ......................................................................... 19

2.2.4 Outcomes in TKA summary ................................................................................. 29

2.3 Factors influencing function in Total Knee Arthroplasty ...................................... 30

2.3.1 Habituation .......................................................................................................... 31

2.3.2 Muscle Function .................................................................................................. 31

2.3.3 Proprioception ..................................................................................................... 33

2.3.4 Prosthetic design ................................................................................................. 34

2.3.5 Range of Motion (ROM) ...................................................................................... 38

2.3.6 Psychological variables ....................................................................................... 39

2.3.7 Joint stiffness ....................................................................................................... 40

2.4 Joint Stiffness ............................................................................................................. 41

2.4.1 Etiology of stiffness in osteoarthritis .................................................................. 42

2.4.2 Aetiology of stiffness following total knee arthroplasty .................................... 47

2.4.2.1 Extra-articular causes ...................................................................................... 47

2.4.2.2 Intra-articular causes .................................................................................... 48

2.4.2.3 Surgical technique ......................................................................................... 48

2.4.3 Measurement of joint stiffness ............................................................................ 51

2.4.3.1 Subjective Measurement of Stiffness ............................................................. 52

2.4.3.2 Passive Resistance to Motion Method ............................................................ 52

2.4.3.3 Pendulum Method ......................................................................................... 64

2.4.3.4 Dynamic Joint Stiffness .................................................................................. 66

2.4.4 Factors affecting joint stiffness ............................................................................ 66

2.4.4.1 Segmental parameters .................................................................................... 67

2.4.4.2 Gender ............................................................................................................. 67

2.4.4.3 Age ................................................................................................................ 68

2.4.4.4 Velocity ......................................................................................................... 68

2.4.4.5 Environmental Conditions ............................................................................ 69
2.4.4.6 Joint fluids ............................................................................... 70
2.4.4.7 Time of day ........................................................................ 70
2.4.4.8 Disuse .............................................................................. 71
2.4.4.9 Joint position ..................................................................... 72
2.4.5 Stiffness summary ................................................................. 72
2.5 Literature Review Summary .................................................... 74

3 Study aims ..................................................................................... 75
3.1 Aims and purpose ................................................................. 75
3.2 Objectives .......................................................................... 75

4 Biomechanical model of joint stiffness ......................................... 76
4.1 Definition of “stiffness” .......................................................... 76
4.2 Development of the mathematic model .................................. 76
4.3 Free body diagram ................................................................. 77
4.4 Development of the biomechanical model ......................... 78
4.4.1 Torque due to gravity ......................................................... 78
4.4.2 Torque due to inertia .......................................................... 79
4.4.3 Passive resistance to motion equation .............................. 81
4.5 Assumptions .......................................................................... 81
4.6 Estimation of anthropometrical data .................................... 82
4.7 Calculation of angular displacement, velocity and acceleration ........................................................................... 83
4.8 Calculation of stiffness parameters ...................................... 83
4.8.1 Passive elastic stiffness ...................................................... 83
4.8.2 Other stiffness related variables ........................................ 84

5 Instrumentation development ..................................................... 85
5.1 System requirements ............................................................... 85
5.2 System Components ............................................................... 86
5.2.1 Passive movement of the lower limb .................................. 86
5.2.2 Measurement of torque ..................................................... 87
5.2.3 Measurement of angular displacement ............................ 93
5.2.4 Passivity of muscles .......................................................... 93
5.2.5 System Assembly ............................................................... 94
5.2.6 Data Acquisition System .................................................. 94
5.2.6.1 Sampling Frequency .................................................... 97
5.3 System Assumptions ............................................................... 98
5.4 Output and data processing ................................................... 98
5.5 Pilot Studies ........................................................................... 101
5.5.1 Ethical Considerations ..................................................... 101
5.5.2 Data Processing ............................................................... 101
5.5.3 Electrogoniometer scaling ............................................... 102
6.7 Data Processing ................................................................. 154
   6.7.1 Questionnaires ......................................................... 155
   6.7.2 Objective measures of function ............................... 156
   6.7.3 Passive resistance to motion data ............................. 156
6.8 Statistical methods .......................................................... 158
   6.8.1 Power and sample size calculations ......................... 158
      6.8.1.1 Calculation of effect sizes ................................. 159
      6.8.1.2 Post-hoc sample size calculations ..................... 160
   6.8.2 Descriptive statistics .................................................. 160
   6.8.3 Inferential statistics ................................................... 161
      6.8.3.1 Differences ...................................................... 161
      6.8.3.2 Relationships ................................................... 162

7 Clinical results ................................................................. 163
   7.1 Participants ................................................................. 163
   7.2 Clinical examination .................................................... 166
   7.3 WOMAC and SF-12 ..................................................... 169
      7.3.1 WOMAC .............................................................. 170
      7.3.2 SF-12 ................................................................. 172
   7.4 Visual Analogue Score for stiffness ............................. 172
   7.5 Self-reported descriptors of stiffness ........................... 174
   7.6 Performance based measures of function ..................... 180
   7.7 Objective measures of stiffness .................................. 185
      7.7.1 Raw stiffness values ............................................. 186
      7.7.2 Normalised stiffness values ................................. 194
      7.7.3 Stiffness threshold angles ..................................... 198
      7.7.4 Normalised threshold stiffness angle ..................... 201
      7.7.5 Passive resistive torque ....................................... 204
   7.8 Relationship between patient reported and objective measures of stiffness ........................................... 208
   7.9 Relationship between stiffness and function ................ 210
      7.9.1 Patient reported stiffness and function .................. 211
      7.9.2 Objective measures of stiffness and function .......... 212
   7.10 Post-hoc sample size calculations .............................. 215

8 Discussion ........................................................................... 217
   8.1 Participant characteristics .......................................... 217
   8.2 Clinical knee examination .......................................... 219
   8.3 Outcomes of TKA ......................................................... 223
      8.3.1 Patient reported outcomes .................................... 224
      8.3.2 Performance based measures of function ............... 231
   8.4 Joint stiffness ............................................................. 233
## Table of Figures

### Chapter 2 - Review of related literature

<table>
<thead>
<tr>
<th>Figure</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1</td>
<td>Hypothetical model depicting the interrelation between joint stiffness and muscle strength (reproduced from [Lung, Hartsell, &amp; Vandervoort, 1996])</td>
<td>45</td>
</tr>
<tr>
<td>2.2</td>
<td>Stress/strain graph</td>
<td>51</td>
</tr>
</tbody>
</table>

### Chapter 4 - Biomechanical Model

<table>
<thead>
<tr>
<th>Figure</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.1</td>
<td>Free body diagram of forces acting on the shank and foot during passive flexion/extension</td>
<td>77</td>
</tr>
</tbody>
</table>

### Chapter 5 - Instrumentation Development

<table>
<thead>
<tr>
<th>Figure</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.1</td>
<td>Acoustic Wave Sensors (Sensor Technologies Ltd, 2004)</td>
<td>90</td>
</tr>
<tr>
<td>5.2</td>
<td>Stiffness rig component linkages</td>
<td>96</td>
</tr>
<tr>
<td>5.3</td>
<td>Flow chart of data processing process</td>
<td>100</td>
</tr>
<tr>
<td>5.4</td>
<td>Bland and Altman plot (mean volts vs difference in volts) for days 1 &amp; 2</td>
<td>103</td>
</tr>
<tr>
<td>5.5</td>
<td>The relationship between the universal goniometer and the electrogoniometer output</td>
<td>104</td>
</tr>
<tr>
<td>5.6</td>
<td>Reliability of electrogoniometer using data in degrees</td>
<td>105</td>
</tr>
<tr>
<td>5.7</td>
<td>Unweighted torque transducer output against angle</td>
<td>109</td>
</tr>
<tr>
<td>5.8</td>
<td>Free body diagram of the torque transducer arm with applied weight</td>
<td>109</td>
</tr>
<tr>
<td>5.9</td>
<td>Starting position of the rig arm and applied spring</td>
<td>113</td>
</tr>
<tr>
<td>5.10</td>
<td>The rig arm having undergone displacement $\theta$ against spring $L$</td>
<td>114</td>
</tr>
<tr>
<td>5.11</td>
<td>X- and y components of the spring force ($F_x$)</td>
<td>116</td>
</tr>
<tr>
<td>5.12</td>
<td>Illustration of differences in sampling frequency</td>
<td>125</td>
</tr>
<tr>
<td>5.13</td>
<td>Sample graph of torque by angular displacement at three sampling frequencies (fast velocity)</td>
<td>126</td>
</tr>
<tr>
<td>5.14</td>
<td>Frequency plot of the displacement signal frequency at a slow speed</td>
<td>130</td>
</tr>
<tr>
<td>5.15</td>
<td>Frequency plot of the displacement signal frequency at a fast speed</td>
<td>130</td>
</tr>
</tbody>
</table>

### Chapter 6 - Methods

<table>
<thead>
<tr>
<th>Figure</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.1</td>
<td>Stair and chair set-up for TUG and Stair ascent/descent test</td>
<td>147</td>
</tr>
<tr>
<td>6.2</td>
<td>Leg extensor power analyser</td>
<td>150</td>
</tr>
<tr>
<td>6.3</td>
<td>Instrumentation for measurement of the resistance to motion</td>
<td>151</td>
</tr>
<tr>
<td>6.4</td>
<td>Electrogoniometer with universal goniometer used for calibration</td>
<td>152</td>
</tr>
<tr>
<td>6.5</td>
<td>Data collection procedure</td>
<td>154</td>
</tr>
<tr>
<td>6.6</td>
<td>Example of a passive resistance to motion vs displacement curve as the knee goes from extension to flexion (flexing)</td>
<td>157</td>
</tr>
<tr>
<td>6.7</td>
<td>Example of a passive resistance to motion vs displacement curve as the knee goes from flexion to extension (extending)</td>
<td>157</td>
</tr>
</tbody>
</table>
Chapter 7 - Clinical Results

Figure 7.1 Knee Society Score by group ................................................................. 169
Figure 7.2 WOMAC stiffness scores by group ....................................................... 171
Figure 7.3 VAS stiffness scores by group ............................................................... 173
Figure 7.4 Scatterplot of self-perceived stiffness score and total number of words used to describe stiffness ................................................................. 175
Figure 7.5 Percentage of participants who used words from the pain category to describe stiffness ........................................................................................................ 177
Figure 7.6 Percentage of participants who used words from the ‘difficulty with movement’ category to describe stiffness ................................................................. 178
Figure 7.7 Percentage of participants who used words from the ‘sensation’ category to describe stiffness ........................................................................................................ 179
Figure 7.8 Normalised leg extensor power by group and gender ......................... 182
Figure 7.9 Walking speed by group and gender ...................................................... 183
Figure 7.10 Fast extension stiffness by group ......................................................... 187
Figure 7.11 Fast flexion stiffness by group ............................................................ 188
Figure 7.12 Average fast midrange stiffness by group .......................................... 189
Figure 7.13 Slow extension stiffness by group ....................................................... 190
Figure 7.14 Slow flexion stiffness by group .......................................................... 191
Figure 7.15 Average slow mid-range stiffness by group ....................................... 192
Figure 7.16 Extension stiffness by velocity ........................................................... 193
Figure 7.17 Flexion stiffness by velocity .............................................................. 194
Figure 7.18 Normalised fast extension stiffness by group .................................. 195
Figure 7.19 Normalised fast flexion stiffness by group ........................................ 196
Figure 7.20 Normalised slow extension stiffness by group .................................. 197
Figure 7.21 Normalised slow flexion stiffness by group ........................................ 198
Figure 7.22 Threshold flexion and extension stiffness angles at fast velocity ....... 199
Figure 7.23 Threshold flexion and extension stiffness angles at slow velocity ...... 200
Figure 7.24 Normalised threshold fast extension stiffness angles by group .......... 202
Figure 7.25 Normalised threshold slow extension stiffness angle by group .......... 203
Figure 7.26 Fast extension threshold stiffness torque by group ......................... 205
Figure 7.27 Fast flexion threshold stiffness torque by group ............................... 206
Figure 7.28 Slow extension stiffness threshold torque by group ......................... 207
Figure 7.29 Slow flexion stiffness threshold torque by group ............................. 208
1 Introduction

Osteoarthritis (OA) has been reported to be the most common form of arthritis affecting up to 25% of adults over the age of 65yrs (Breedveld, 2004). The knee joint is the second most commonly involved joint and symptoms include pain, functional limitations and stiffness. As the disease progresses these symptoms increase in their severity and when conservative treatments can no longer provide relief, total knee arthroplasty (TKA) has become the treatment of choice (Jordan et al., 2003; Martin, Scott, & Thornhill, 1998). The rates of primary TKA have been increasing steadily. In 2008, 6160 primary TKA procedures were performed in Scotland alone, an increase of 64% since 2004 (Scottish Arthroplasty Project, 2009). Osteoarthritis was the primary diagnosis in over 90% of the procedures (Scottish Arthroplasty Project, 2004). Studies of outcome in TKA have shown that following surgery, pain is decreased and function is improved (Bachmeier et al., 2001; Heck et al., 1998). Although for the majority, TKA is a successful procedure, functional limitations have been demonstrated in up to 30% of patients post-TKA (Boonstra, De Waal Malefit, & Verdonschot, 2008; Dickstein et al., 1998; Lingard et al., 2004; Noble et al., 2005). The reasons for post-operative functional limitations are however unclear. Poor self-reported function has been shown to be associated with higher self-reported knee joint stiffness (Maly, Costigan, & Olney, 2006; Noble et al., 2006) although measures of knee joint stiffness so far have been simple. Only one patient reported outcome measure (the WOMAC) includes a stiffness dimension and there are no commercially available systems for the objective measurement of stiffness. True stiffness has been defined as the force required to produce a given displacement (or in terms of joint rotations, the torque required to produce a given angular
displacement) (Gajdosik, 2001; Latash & Zatsiorsky, 1993). No studies have attempted to quantify knee joint stiffness in the replaced knee using this definition and thus it is unknown how well self-reported measures represent true stiffness. As a result, it is not known to what extent self-reported stiffness represents a physical impairment and thus the nature of any association between functional limitations and stiffness could not be evaluated.

Further knowledge of the extent to which ‘stiffness’ is a physical impairment and its impact on function, could be useful to clinicians when planning strategies to help patients to maximise their recovery following TKA. Furthermore, expectations have been shown to be one of the most significant factors that influence satisfaction with TKA surgery (Mahomed et al., 2009). A greater understanding of the factors that influence functional ability following TKA could be of use to orthopaedic surgeons, nurses, physiotherapists and other members of rehabilitation teams in ensuring that patients get the most appropriate advice and guidance on what to expect following TKA.
2 Review of the related literature

This chapter provides an outline of the changes that occur in with osteoarthritis (OA) and the evaluation of outcomes after total knee arthroplasty (TKA) with particular reference to the evaluation of joint stiffness. Outcomes in TKA are explored and methods for assessing outcomes evaluated in order to develop a rationale for studying knee joint stiffness.

2.1 The Aging and Osteoarthritic Knee Joint.

As joints age, changes occur within the articular cartilage. These include decreased water content, reduced tensile strength and increased stiffness of collagen, decreased glycosaminoglycan chain length and fragmentation of linking glycogens (Atkinson, Coutts, & Hassenkamp, 2005). These changes however are not necessarily associated with joint degeneration and are different to the changes seen in osteoarthritis (OA). In OA, articular cartilage typically displays increased water content, which leads to increased permeability and reduction in strength and decreased stiffness (Miller, 2004). OA however does not affect the articular cartilage in isolation. Changes may also seen in the subchondral bone, ligaments, capsule, synovial membrane and periarticular muscle (Nuki, 2002). Suggested changes include hypertrophy of the periarticular muscles, minute tears in the capsular tissue and chronic synovitis (Hough, 2005).

OA can be idiopathic or secondary to a variety of factors such as trauma, metabolic disease or a pre-existing inflammatory disease (Nuki, 2002). Clinically, such a joint may be asymptomatic but as the disease progresses, symptoms of pain, loss of movement and altered function become apparent (Breedveld, 2004). Criteria for the
classification of idiopathic osteoarthritis (Table 2.1) have been defined by the American College of Rheumatology (Manek & Lane, 2000) and included a criteria of stiffness.

Table 2.1 Criteria for the classification of idiopathic osteoarthritis

<table>
<thead>
<tr>
<th>Clinical criteria for classification of idiopathic osteoarthritis</th>
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<tbody>
<tr>
<td>Pain</td>
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<td>Plus one of:</td>
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<tr>
<td>- Age &gt; 50 years</td>
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<tr>
<td>- Stiffness of &lt; 30mins duration</td>
</tr>
<tr>
<td>- Crepitus</td>
</tr>
<tr>
<td>- Bony tenderness</td>
</tr>
<tr>
<td>- Bony enlargement</td>
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<tr>
<td>- No palpable warmth</td>
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Stiffness as a criteria was worthy of further discussion as there has been no published guidance on how it should be defined. There have been no clinical definitions of stiffness published nor are there any instruments for use in a clinical environment which can objectively measure stiffness; therefore, assessment of the stiffness criteria must rely upon the patient and/or clinician’s own understanding of what stiffness means. A previous study (Rhind, 1987) of stiffness in rheumatoid arthritis, indicated that patients’ definitions of stiffness were ambiguous. A range of words were used to describe stiffness including words which related to pain, movement difficulty, functional difficulty and sensations. There has been no similar work conducted on patients with OA and thus it is not known how these patients interpret ‘stiffness’. If similar ambiguities to RA patients exist in OA, this could cast doubt upon the robustness of stiffness as a diagnostic criterion for OA. Although no clear definition of stiffness exists, it has been clearly shown to have a significant impact on the lives of those with OA. A qualitative study of the experiences of patients with hip and
knee OA (Gooberman-Hill et al, 2009) revealed that ‘stiffness’ was the third most frequently used term by those with knee OA when describing the pain and limitations associated with their knee. The authors went on to conclude that stiffness was used to describe the relationship between changes in movement/position and pain. As a qualitative study however, the interpretation of comments such as ‘…when I get up there is an extreme amount of stiffness’ were potentially influenced by the bias of the researcher. No quotes were given that specifically stated that patients perceived stiffness to describe the relationship between changes in joint position and pain and therefore the conclusions relating to stiffness cannot be considered as robust.

In symptomatic osteoarthritis, the first choice of treatment is usually conservative. These methods include advice and reassurance, walking aids, orthotics, physiotherapy, non-steroidal anti-inflammatory drugs (NSAIDs), analgesics and very occasionally intra-articular steroid injections (Dandy & Edwards, 1999; Breedveld, 2004). As the arthritis progresses and when all of these non-surgical treatment options have been explored, if the patient continues to suffer from unacceptable levels of pain and physical dysfunction, joint replacement (arthroplasty) has become the accepted treatment of choice (Hawker et al., 1998; Jordan et al, 2003; Martin, Scott, & Thornhill, 1998).

2.2 Outcomes in Total Knee Arthroplasty

As the purpose of TKA is primarily to relieve pain and improve functional ability, the success of TKA is usually considered by the extent to which these aims have been achieved. There are three broad methods by which outcomes data may be elicited: 1) clinical outcomes as reported by the surgeon, 2) patient reported measures and 3) objective measures of function.
2.2.1 Clinical Outcomes

Orthopaedic surgeons have long attempted to grade the measure of success of joint arthroplasty. An arthroplasty was often considered successful if it had good alignment of the components, good fixation with few radiolucent lines, adequate range of motion, and survivorship (Font-Rodriguez, Scuderi, & Insall, 1997; Rand & Ilstrup, 1991; Wright et al., 1990). Rating systems were designed to provide an easy, standardised method of recording outcomes. Most compute a score based on the evaluation of a range of variables and then assign a related descriptive label to various scores to give an outcome such as ‘poor’, ‘fair’, ‘good’ and ‘excellent’.

There are however many rating systems. Drake et al. (1994) undertook a review of the rating systems used to report outcomes in the orthopaedic literature and found that in 210 studies published between 1972 and 1992, 34 different rating systems were used. These systems displayed considerable diversity in the composition of their scoring systems. Scores had various ranges, used different summation techniques, gave different contributions to the overall score for single items such as pain and used different activities of daily living to assess function. As a result it was difficult to compare results from different rating systems. A final and perhaps more worrying aspect was that Drake et al (1994) could not find any study which described the validity or reliability of any of the rating systems in their review.

Despite this, there are numerous studies reporting good to excellent clinical results at up to 10 years post-surgery using the rating systems described above (Aglietti et al., 1999; Ewald et al., 1999; Li, Zamora, & Bentley, 1999; Loughead et al., 2008; Malkani et al., 1995).
Since the earlier review by Drake et al. (1994), some further work has been established on the reliability of some of the scoring systems described. The Knee Society Score (KSS) (Insall et al., 1989), the Hospital for Special Surgery Score (HSS), the Hungerford Score and the Bristol Score are all scores based on reports of pain, alignment of the joint, stability of the joint and range of motion (active and passive) and provide a score out of 100. Using Kendalls Tau, Bach et al. (2002) found that interrater reliability of the first three scoring systems was poor for several dimensions: stability (0.07 – 0.53), knee alignment (0.22 – 0.54) and muscle strength (0.48 – 0.65). Pain was more reliable (0.62 – 0.88). However, there was no attempt to determine how well measures such as pain, agreed with the patients self-report of pain thus limiting any claims of validity. Other, more objective factors (range of motion flexion contractures, extensor lag, walking distance and walking aid) were also found to be reliable.

Once the overall score has been summed, an outcome classification such as excellent, good, fair or poor is attached to the final score. Bach et al (2002) went on to reveal that the Hungerford Score and Knee Society Score had a poor capability of distinguishing between excellent or good and fair or poor results.

However, regardless of the label, studies have indicated that it is possible for a patient to have a technically good outcome, with good alignment of the prosthesis, good fixation, good range of movement and yet to continue to have pain and poor function in their activities of daily living (Fisher et al., 2007; Kantz et al., 1992; Lieberman et al., 1996; Meijerink et al., 2009; Patt & Mauerhan, 2005). Thus clinician derived measures of outcome have become less popular.
2.2.2 Patient reported outcomes

In 1988, Gartland called for orthopaedic surgeons to focus less on technical outcomes and concentrate more on the impact of their expensive procedures on the health and well-being of their patients. Rivest & Liang (1998) commented in their review of outcome measures, that patient derived outcome data was valid and reliable as well as sensitive to change when compared with traditional clinician derived findings, although they offered no evidence to support this statement. A later study (Bullens et al., 2001) claimed to have found only a poor association between physician assessed outcomes and patient satisfaction although the correlation coefficient was calculated to be 0.62; a value which is generally considered to represent a moderate association (Munro BH, 2001). Further evidence for a disparity between a surgeon’s opinion and the patient’s interpretation of outcome was offered by Meijerink et al (2009), who found poor correlations between surgeons’ satisfaction with surgery and the patients’ satisfaction with surgery adding further evidence that patient derived outcomes are important.

As a result, larger numbers of studies have since reported patient derived outcomes. Unfortunately, many studies reported within the literature have been undertaken within the United States (US) and it has been recognised that there were considerable differences in outcomes between patients undergoing TKA in the United Kingdom (UK) and the US (Lingard et al., 2000; Lingard et al, 2004). Thus it was difficult to extrapolate these results to a UK population whom Lingard et al (2000) have suggested, have significantly worse functional outcomes than their counterparts in the US.
2.2.2.1 Questionnaires

Since the 1980’s there has been an increase in the number of patient-reported outcome instruments used to evaluate TKA, some with greater evidence to support their reliability and validity than others. The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) (Bellamy et al., 1988), the SF-36 (and subsequently the SF-12) (Ware & Sherbourne, 1992), the Oxford Knee Score (Dawson et al., 1998), the Knee Injury and Osteoarthritis Outcome Score (KOOS) (Roos et al., 1998) and the Lower Extremity Functional Scale (LEFS) (Jogi, Kramer, & Birmingham, 2005) are just a few examples. These questionnaires all require completion by the patient and have dimensions that evaluate function and pain. In addition the WOMAC has a stiffness dimension although this aspect is only covered by two questions (Table 2.2).

Table 2.2 WOMAC stiffness questions

<table>
<thead>
<tr>
<th>How severe is your stiffness after...</th>
<th>None</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
<th>Extreme</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. ...first wakening in the morning?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>2. ...sitting, lying or resting later in the day?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

The WOMAC function scale has been shown to be the most responsive to change following TKA compared to; 1) the six minute walk test, 2) gait velocity, 3) stair ascent time, 4) the SF-36 role physical and physical functioning subscales and 5) the Knee Society Score (Kreibich et al., 1996; Parent & Moffat, 2002). Responsiveness was evaluated on the basis of the size of the t-statistic (values before and after surgery were compared) and highly significant differences were found following
surgery using all outcome measures. Responsiveness however can be assessed using
a range of indices and Wright & Young (1997) showed that the ranking of different
outcome measures according to responsiveness differed depending on which index
was used.

Consequently, it has been claimed that the WOMAC is the leading self-report
outcome measure for osteoarthritis of the lower extremity (Bellamy, 1997; Dougados
et al., 2000). It should be recognised however that the authors of these two papers
included the original author of the WOMAC and therefore could potentially have
been biased in their conclusions. Despite this, WOMAC pain and function subscales
were recommended by the Outcome Measures in Rheumatology Clinical Trials
group (OMERACT) (Bellamy et al., 1997) as an outcome measure for patients with
osteoarthritis of the knee. WOMAC has also been recommended by UK based
researchers for use in evaluating the results of surgery subsequent to OA (Brazier et
al., 1999).

Many studies have reported WOMAC scores in their evaluation of outcome
following TKA (Bachmeier et al, 2001; Boonstra, De Waal Malefit, & Verdonschot,
surveyed 1193 patients who had undergone TKA between 2 and 7 years post-op and
stratified the results by geographic area. A sample of patients taken from the US as a
whole (n = 487) reported a mean WOMAC pain score of 18.4 (compared to 58.2
prior to surgery) and a mean WOMAC function score of 27.7 (these scores were
transformed to a 0 - 100 scale where 0 represents no difficulties and 100 represents
extreme difficulties). Pain relief and functional ability were significantly improved
but this retrospective study was limited in that it relied on patient recall and did not
calculate WOMAC function scores prior to surgery. In their study of 291 patients at 2 years following surgery, Heck et al (1998) reported significant improvements in the WOMAC pain subscale score from 16.1 prior to surgery to 7.9 at 2 years post-op (possible range 5-25, high score indicates extreme pain). The function subscale score also showed significant improvements from 55.1 to 31.2 (possible range 17-82, high score representing extreme difficulties). The results from this study could be considered more robust as a result of its prospective design, large sample size and good follow-up rate at 2 years (92%). Bachmeier et al (2001) also found significant improvements in pain (10.8 pre-operatively compared with 5.1 post operatively), function (38.3 pre-operatively compared to 21.8 post-operatively) and stiffness (4.7 pre-operatively compared to 2.7 post-operatively) at 1 year post-TKA. Although Bachmeier et al (2001) used the WOMAC in its Likert scale format, scores were normalised to a 0-100, worst to best scale. Although generally significant improvements in WOMAC function have been reported, function scores remain significantly worse at 1 year post-surgery, when compared with healthy controls (Boonstra, De Waal Malefit, & Verdonschot, 2008; Finch et al, 1998).

The results of these studies have highlighted two aspects. Firstly, based on the statistics, TKA achieves its aims of reducing pain and improving function when evaluated using patient reported data. There is however a difference between statistically significant and clinically significant differences. With large sample sizes, it is possible to find statistically significant differences even if the observed difference is quite small. Thus the concept of clinically important differences should also be considered. Escobar et al. (2007) reported that a difference of around 15 points on the WOMAC sub-scales (where the scales were normalised to 0-100) was
required in order for differences to be meaningful to the patient. Secondly, they also highlight the variability of reporting WOMAC subscales in the literature i.e. 5-point Likert scales, VAS scales, normalised to a 100 point scale. Heck et al (1998) used the 5-point Likert scale, Hawker et al (1998) did not state which scale was used but subsequently converted the score to a 100 point scale and Finch et al (1998) used the visual analogue scale (VAS) version of the WOMAC. Although both the Likert scale and VAS have been validated in the original papers, care must be taken to observe the method of scoring utilised when attempting to compare outcomes between studies.

Although the WOMAC is a recommended outcome measure and has well established internal consistency and test-retest reliability (particularly for the pain and function subscales) (McConnell, Kolopack, & Davis, 2001), some authors have questioned the factorial validity of the measure. Factorial validity is defined as “the extent to which domains hypothesised to make up a measure actually underlie patients responses” (Kennedy et al., 2003). Several studies have concluded that the function subscale can be erroneously influenced by patients’ responses to the pain subscale. Consequently, it has been claimed that the WOMAC physical function subscale may be limited in its ability to report changes in function accurately, particularly if the patterns of pain and function in a patient are different (Kennedy et al, 2003; Ryser et al., 1999; Stratford & Kennedy, 2004; Terwee et al., 2006a). Kennedy et al (2003) reported poor factorial validity of the WOMAC score based partly on the fact that significant changes were found in two other measures of function. Interestingly the two other functional outcomes measured were self-paced walk test (SPWT) and the Timed Up and Go, the validity of neither of which has been fully established for the
measurement of function in an arthroplasty population. The study was further limited by its retrospective design. WOMAC scores had been extracted from client medical notes, by a researcher and there was no explanation of how this had been undertaken. Therefore, until these conclusions have been verified by further research, the results must be viewed with caution. Other evidence (Lingard et al, 2004; Terwee et al., 2006b; Wolfe, 1999) has suggested that WOMAC scores, like other questionnaires, may be influenced by psychological and non-disease specific factors such as low back pain and fatigue and therefore such factors should be taken into account in any subsequent analyses.

Using the WOMAC as a gold standard, a team of researchers from the University of Western Ontario (Jogi, Kramer, & Birmingham, 2005) published a further questionnaire (the Lower Extremity Functional Scale (the LEFS)) which they claimed had two particular advantages over the WOMAC. The LEFS is shorter by 4 questions and is presented over 1 page rather 4 as in the WOMAC and it is claimed that it has greater generalisability to other lower extremity orthopaedic conditions. However the study participants did not report any particular preference of one over the other and no strong rationale was presented for the use of the LEFS rather than WOMAC.

In addition to a condition specific measure, it has been suggested that studies should also report a generic health status measure, such as the SF-36 (and the later SF-12), particularly where subjects (such as the elderly) may also present with a number of comorbid conditions (Brazier et al, 1999; Dunbar et al., 2001; Hawker et al., 1995).

At 3 months following TKA, Sharma et al, (1996) reported significant improvements in the domains of Physical Functioning (mean = 56.7), Social Functioning (mean =
87.8) and Bodily Pain (mean = 58.6). No differences were seen in Role-Emotional and Mental Health domains. It was not stated why the remaining 3 domains of Physical Role Functioning, Vitality and General Health perceptions were not reported. Heck et al (1998) also reported improvements in the physical composite score at 6 months post-op, with the scores remaining similar at 2 years post-op. Mental composite scores remained stable. Individual SF-36 domain scores were reported but were not statistically analysed. Although improvements were seen in all the above studies, scores generally remained below reported US norms reported by Ware et al (1992).

Dawson et al (1998) claimed that the Oxford Knee Score was superior to the WOMAC and the SF-36, as it is knee specific and is quicker and easier to process. In addition the Oxford Knee Score appeared to be more sensitive to change than the SF-36. These claims were subsequently corroborated in a large scale study of Swedish patients undergoing TKA (Dunbar et al, 2001). A later study (Harcourt, White, & Jones, 2001) however found that the score was not as specific to the knee as had been previously claimed when hip or spinal pathology was present and advised caution when summing scores derived from both pain and functional data.

A more recent report of a new functional questionnaire (the Total Knee Function Questionnaire (Weiss et al., 2002)) showed that although in general TKA was successful at relieving pain, many patients still had significant difficulties in performing activities that they perceived as being important. The Total Knee Function Questionnaire comprises of questions on each of 55 functional activities grouped into four categories; baseline activities, advanced activities, recreational activities and exercises. For each activity, patients indicated the prevalence of
participation in each activity, importance of the activity and limitations in doing each activity. Although more comprehensive than other functional questionnaires such as the WOMAC (which contains 17 questions on function), there has been no evaluation of the validity, reliability or responsiveness of the questionnaire. Compared with controls the TKA patients appeared to have overall lower function scores (Noble et al, 2005). The paper does not make it clear however if differences between the control and TKA group were statistically or clinically significant. Activities in which scores appeared to differ the greatest were kneeling, squatting, moving laterally, turning and cutting, carrying loads, stretching, leg strengthening, tennis, dancing gardening and sexual activities. Although these activities were also limited in the control group, a greater proportion of subjects in the TKA group reported difficulties and the composite scores were worse. Although the questionnaire lacks evidence of its psychometric robustness, the results of this large study by gave an insight into the functional limitations that has not been reported elsewhere.

This type of questionnaire based approach has the advantage of allowing large numbers of participants to be studied, statistical inferences to be made and findings generalised to a larger population. It has also claimed been that questionnaires have a low chance of bias and a good level of reliability possible (Sarantakos, 1998). Thus currently, the large number of studies that have used questionnaires confirmed that the questionnaire is the most popular method of obtaining patient-derived outcome data.

Despite these advantages, large scale questionnaire studies are not without problems. The Musculoskeletal Outcomes Data Evaluation and Management System
(MODEMS) (Saleh et al., 2004) identified that many studies only reported on small numbers of patients, frequently in retrospect or using short-term follow-up or using a range of different outcome measures that were not always validated. Thus MODEMS set out to address some of these issues by undertaking a large scale outcomes study. The target was to create a database of 50,000 patients, over two years, using validated questionnaires, which it was hoped, would become the gold standard for musculoskeletal research. However the study encountered numerous problems including poor recruitment and follow-up. The goal of creating validated questionnaires which could be used as a gold standard claimed to have been attained. However, the outcomes used to evaluate TKA, other than the SF-36, were not clearly stated and little can be drawn from the lessons learnt. Other countries appear to have been more successful in their attempts to create large scale registers of patients undergoing joint arthroplasty. The Swedish Knee Arthroplasty Register which began in 1975 is one such register (Robertsson et al., 2000). There are several reports from the data held on the Swedish register (Dunbar et al, 2001; Robertsson et al., 1999; Robertsson & Dunbar, 2001) which routinely collects information on number of operations, types of implant and survivorship. The Scottish Arthroplasty Project also provides yearly reports (Scottish Arthroplasty Project, 2009) of routinely collected data such as volumes of primary and revision hip and knee arthroplasties undertaken in Scotland, diagnosis, survival rates, length of stay, patient characteristics and complications. Similar joint registries are undertaken in England & Wales, Australia, New Zealand, Norway and Canada.

More recently, patient satisfaction with surgery has begun to receive greater attention. Satisfaction has been perceived to be a more accurate reflection of the
patients opinion of their surgery than the more commonly observed measures of pain and function (Bullens et al, 2001) and has been thought to be influenced by range of factors. Factors which have been proposed include; post-operative functional ability (Baker et al., 2007; Noble et al, 2006), pain relief (Baker et al, 2007; Baumann et al., 2006; Berges et al., 2006), social functioning (Baumann et al, 2006) and stiffness (Noble et al, 2006). One of the strongest influencers of satisfaction however has been shown to be patient expectations of surgery (Mahomed et al, 2009; Noble et al, 2006). Expectations of TKA were linked with knowledge of the procedure and its outcomes; information which was provided by a range of sources including friends, family and medical staff (Hall et al., 2008).

2.2.2.2 Qualitative research

Although questionnaires are undoubtedly the most popular method of providing outcome data following TKA, critics of quantitative approaches have claimed that many survey techniques are ‘sterile’ and that it is difficult to capture the essence of a subjects experience of health and social well being using numbers (Berg, 2001; Malterud, 2001; Polgar & Thomas, 2000). Rather than measuring quantity, qualitative research seeks to explore “concepts, definitions, characteristics, metaphors, symbols and descriptions of things” (Berg, 2001). Thus, through in depth discussion with the participant, a persons experiences, beliefs and meaning attributed to these experiences can be elicited in a way that questionnaires cannot (Grobich, 1999). Despite these apparent advantages, there have been very few qualitative studies undertaken in the field of orthopaedics, perhaps reflecting the scepticism with which the medical community regards such an approach. Orthopaedic outcomes research is undoubtedly dominated by a quantitative approach. This focus is clearly
demonstrated in paper on measurement of functional ability by (Liang & Jette, 1981) who quoted Lord Kelvin (1824-1907) “When you cannot measure it, when you cannot express it in numbers, you have scarcely, in your thoughts, advanced to the stage of science, whatever the matter may be”.

Daly (2004) explored the experiences and beliefs of 6 patients who had all been identified as having ‘low’ SF-12 scores. In all cases the surgery was considered successful by the attending surgeon. Interestingly, 2 out of 6 patients reported a positive outcome and did not appear to have any functional limitations despite reporting ‘low’ scores on their SF-12 form. This may bring into question the validity/reliability of such questionnaires but the issue was not explored in any further detail. One theme that was identified was poorer than expected (from the patients perspective) outcomes, which supports evidence from quantitative research that patient expectations prior to surgery can strongly influence their satisfaction with the outcome (Dickstein et al, 1998). The study however by Daly (2004) was only an uncorrected MSc dissertation and therefore potentially limited in the conclusions that could be drawn from it.

Although qualitative research provides rich data and allows a comprehensive in-depth exploration of a topic, its’ critics claim that it is too subjective, lacks reliability, has questionable external validity and is not generalisable to the wider population (Silverman, 2000).

Choice of approach is strongly influenced by the nature of the problem to be addressed. Qualitative approaches are most appropriate for research questions that relate to values, beliefs, behaviours and meanings (Whalley-Hammell, Carpenter, & Dyck, 2000).
2.2.3 Objective measures of outcome

Although patient reported measures of function are useful in providing outcome data, it has been suggested that some aspects of physical functioning are not covered by self-reported measures and that they should be supplemented with performance based measures of function (Boonstra, De Waal Malefit, & Verdonschot, 2008; Finch et al, 1998; Parent & Moffat, 2002; Stratford & Kennedy, 2006; Witvrouw et al., 2002). The relationship between patient reported and performance based measures of function has been shown to be at best, only moderate (r = 0.4 - 0.6) (Cress et al., 1995; Finch et al, 1998; Gore et al., 1986; McCarthy & Oldham, 2004; Mori, Lundon, & Kreder, 2005; Piva et al., 2004; Rowe, Myles, & Nutton, 2005; Witvrouw et al, 2002), which further supported the suggestion that self-reported and performance based measures do in fact measure different domains of function. This lack of statistical correlation has also been attributed to measurement error and validity of performance based tests and these issues will be discussed further in relation to specific measures.

There has been a variety of different approaches to the objective measurement of function. These have included laboratory based motion analysis, field based measures of ROM, timed measures of individual activities, aggregated timed activity measures, accelerometer based measures and measurement of activity levels.

Complex motion analysis has offered useful insights into tempo-spatial gait parameters, knee joint kinematics and joint loading. Persistent abnormalities in gait following TKA have been observed by several authors (Andriacchi, Galante, & Fermier, 1982; Benedetti et al., 2003; Berman et al., 1987; Bolanos et al., 1998; Dorr
et al., 1988; Steiner, Simon, & Pisciotta, 1989). Characteristics of gait post-TKA included reduced knee flexion during stance, at push-off and during swing, reduced velocity and step-stride length. Although Benedetti et al (2003) also undertook a clinical assessment; there was no attempt to explore the relationship between functional scores and gait abnormalities. Viton et al. (2002) explored equilibrium and movement control strategies in an attempt to explain the persistent gait abnormalities seen following TKA. Movement asymmetries were noted following TKA although some aspects relating to ‘preparation to step’ reached values similar to controls. Time taken for weight to be accepted onto the supporting limb remained longer and a whole body movement of the trunk was noticed in preparation for the step rather than just the upper body which occurred in the control group.

Although the studies described above have been shown to be able to provide additional information on outcomes in TKA, they utilised motion analysis; a complex laboratory based approach, which limits the external validity of the findings. It was also expensive, which restricted the potential sample sizes and limited the extent to which the results could be generalised. Consequently this approach has been most useful in answering very specific questions about the nature of TKA rather than for larger scale outcome studies.

Field based motion analysis however can be carried out, albeit with a limited range of variables, by using electrogoniometers to measure joint kinematics. Myles et al. (2001) investigated a larger sample of subjects undergoing a wide range of functional activities using a portable electrogoniometer system. Patients undergoing TKA (n = 50) were compared with a group of age-matched controls (n = 20). It was found that the TKA group had a significantly less mean peak flexion arc (compared to the
control group) in the affected knee, during all 11 activities, prior to surgery and also at 4 and 18-24 months post-operatively. At 18-24 months post surgery, TKA patients also failed to increase significantly their mean peak flexion arc from that measured prior to surgery. Interestingly, the TKA patients also failed to utilise the active ROM available in the knee. For example, the maximum knee excursion at 18-24 months post-surgery was 76° (during sit-to-stand) compared to an available 96° (active ROM measured on an examination couch). The maximum knee excursion utilised by the control group was 135° (during in/out of a bath) compared to an available 137°. These values tended to agree with earlier studies (Dorr et al, 1988; Jevsevar et al., 1993) who used laboratory motion analysis systems to evaluate the kinetics and kinematics of gait, sit-to-stand and stair ascent/descent following TKA. In a later paper, the same authors (Rowe, Myles, & Nutton, 2005) attempted to investigate the relationship between ROM during functional activities and the physical component summary of the SF-36. A weak relationship was revealed although it should be noted that the SF-36 is not a joint specific measure of function, rather it is a measure of generic quality of life and other studies have suggested that such measures can be heavily influenced by factors such as mental health and co-morbidities (Jones, Voaklander, & Suarez-Almazor, 2003; Lingard et al, 2004). The weak correlation between ROM and patient reported measures of function however has also been reported by other authors (Miner et al., 2003).

Weight bearing activities such as walking and stair climbing are considered basic activities of daily living (Bergstrom et al., 1985; Weiss et al, 2002) and have been shown to be affected by knee osteoarthritis (Childs et al., 2004; Guccione et al., 1994). Thus, many studies have reported timed tests in the evaluation of locomotor
function in OA and TKA patients (Collopy et al., 1977; Dorr et al., 1988; Finch et al., 1998; Freter & Fruchter, 2000; Kennedy et al., 2003; Kreibich et al., 1996; McCarthy & Oldham, 2004; Mori, Lundon, & Kreder, 2005; Parent & Moffat, 2002; Rivest & Liang, 1998; Stratford & Kennedy, 2006; Walsh et al., 1998). Of the few that used the measures to evaluate outcome in TKA, most, (Collopy et al., 1977; Dorr et al., 1988; Kreibich et al., 1996; Parent & Moffat, 2002), found significant improvements between pre and post-op measures with the exception of Stratford & Kennedy (2006) who found that self-reported measures of pain and function improved whilst performance based measures deteriorated. The median time however to post-operative assessment was only 53 days which may account for these results. Unfortunately only one study compared the results of performance based measures of function in patients with TKA with a control group (Walsh et al., 1998). Unfortunately Walsh et al (1998) did not look at TKA patients pre-and post surgery but they did find that TKA patients were significantly slower than controls in self-paced walk test (SPWT), fast SPWT (where participants were asked to walk quickly) and ST (stair time).

Timed walk tests have been a common feature of performance based measures. The SPWT, fast SPWT and 6-minute walk test (6MWT) have all been shown to be reliable (ICC 2,1 > 0.9) and responsive to change following TKA (although less so than the WOMAC and the KSS) (Kennedy et al., 2005; Kreibich et al., 1996; Parent & Moffat, 2002). Despite the evidence to suggest good reliability, Stratford et al. (2003) questioned the content validity of several performance based measures of function including the SPWT after determining that the correlation of these scores with a patient self-reported measure (the Lower Extremity Functional Scale) was
low. Although they concluded that performance based measure of function perhaps
do not measure the full breadth of health concepts compared to a self-reported
measure, it was recognised that this may in part be due to patient interpretation of the
word ‘difficulty’ used in the questionnaires. Terwee et al (2006b) criticised the
conclusion made by Stratford et al (2003), suggesting that the results supported
evidence for the lack of content validity of the self-reported measures of physical
functioning, not the performance based measures. They argued that the results of
Stratford et al (2003), like their own, showed that self-reported measures of physical
functioning were influenced by a combination of pain and function. These findings
supported arguments that self-reported and performance based measures of function
may well be influenced by different factors and therefore using one to establish
validity of the other is not a sound approach. Interestingly, the same group of
researchers (Kennedy, 2004) later went on to study MDC (minimal detectable
change) in the same battery of measures and suggested that a change of 4.04s (fast
SPWT) and 61.34m (6MWT) was required in order to be able to monitor change
reliably in patients undergoing TKA. However, although the 6MWT has been shown
to be more responsive to change than other timed walk tests, there were some issues
which may limit its usefulness as an outcome measure in TKA. Firstly, the test was
initially proposed as a measure of cardiorespiratory fitness, (Butland et al., 1982) and
has been recommended for use particularly in the assessment of interventions for
severe heart and lung disease (American Thoracic Society, 2002). It was therefore
designed primarily as a measure of endurance rather than for functional ability.
Furthermore it could be strongly influenced by co-morbid diseases in patients with
TKA. Secondly, from a more practical standpoint, the American Thoracic Society
stated that it should be performed indoors, on a long, flat straight corridor at least 30m in length. In addition, the corridor must be rarely used in order to provide a quiet environment in which to undertake the test. In many busy UK hospitals, there is rarely a ‘quiet’ 30m corridor which would be suitable. In determining the factors that could explain the variability of the 6MWT, Harada, Chiu, & Stewart (1999) noted that up to 54% of the variability in the 6MWT could be explained by a quick and simple 8 metre walk. McCarthy & Oldham (2004) evaluated a timed 8m walk in OA patients as part of an aggregated locomotor function (ALF) score and found good reliability for both the walk component (ICC = 0.98) and the overall ALF score (ICC = 0.99). The study also claimed the aggregated score to be valid however the conclusions were limited by the analysis of criterion validity, which was assessed against the ‘gold standard’ of the physical function subscales of the SF-36 and WOMAC scores using simple correlation coefficients (Spearman’s Rank). The advantage of the 8m walk was that it was quick and easy to administer as part of a battery of tests and less likely to be influenced by the cardiorespiratory status of the subject. By increasing the distance of the short walk to 13m however, 90% of the variability in the 6MWT could be explained (Mori, Lundon, & Kreder, 2005). Other studies have found the 13m walk test to be reliable in the elderly (Marks, 1995).

Although walking is an important aspect of locomotor function, timed walk tests are simple and tend not to be too physically challenging. Everyday activities require more than just the ability to walk and therefore other timed locomotor tests are also often used to assess more advanced aspects of function. The ‘Timed Up and Go’ (TUG) test was first introduced as a measure of functional mobility in an elderly

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1 TUG protocol – from a seated position, rise, walk 3m, turn round, walk back to chair and sit down.
geriatric day hospital population (Posiadlo & Richardson, 1991) but variations of the test have more recently been described in studies of orthopaedic populations. Freter & Fruchter (2000) studied the relationship between the TUG and gait speed in an orthopaedic population but considered that it was not necessary to evaluate the reliability as both tests were claimed to have ‘known acceptable reliability’. A similar attitude to reliability was demonstrated by Mori, Lundon & Kreder (2005) in their correlational study of a timed walk test with, amongst others, the TUG in an elderly orthopaedic population. They concluded that although the 13m walk test was strongly correlated with the TUG, both tests provided different but equally useful information related to physical function. Use of the TUG for pre-operative and post-operative evaluation of function was also reported by Kennedy et al (2003) however differences in the timing of pre/post operative periods makes comparisons with Freter and Fruchter (2000) invalid. Piva et al (2004) reported the use of the Get Up and Go (GUG\(^2\)) and although reliability was established (ICC 2,1 > 0.9), a different protocol was used making comparisons with the original protocol (used by Freter and Fruchter (2000) and Kennedy et al (2003)) difficult. A later study by Kennedy et al. (2005) using the original protocol by Posiadlo (1991) reported an ICC (2,1) of only 0.75. They went on to explain that the reliability of a measure intended for individual use must be greater than that intended for group use and that according to Nunnally & Bernstein (1994), a value of 0.75 may not be adequate. However, the measure does appear to have face validity. Getting out of a chair requires knee mobility and strength – both factors influenced by OA and TKA. Walking and turning movements are also limited (Walsh et al, 1998; Weiss et al, 2002) and thus it would appear that

\(^2\) GUG protocol – from a seated position, rise, walk 50ft (15.2m)
the TUG measures several of the variables limited before and after TKA. Piva et al (2004) however suggested that the GUG test has questionable validity in evaluating function in an OA population. They found only a moderate correlation with patient reported measures of physical function (WOMAC r = 0.39, SF-36 r = -0.44) and concluded that the GUG under represents the construct of physical function. Using patient reported measures of function as a gold standard, against which the concurrent validity of a performance measure of function is evaluated, has already been questioned in the current study and thus such conclusions may not be appropriate. The timed chair transfer test, evaluated as part of the ALF score (McCarthy & Oldham, 2004) is similar in protocol to the TUG/GUG. It involves walking to a chair, sitting down, standing up and walking back to the start and good reliability has been demonstrated (ICC (2,k) = 0.99).

Stair climbing also requires knee mobility and strength and timed ascent/descent has also been described as an outcome measure in TKA. Stair time has been deemed to be reliable and responsive (Walsh, 1998; McCarthy and Oldham, 2004; Kennedy, 2005) in the evaluation of function following TKA. Perron, Malouin, & Moffat (2003) suggested that stair climbing is a more advanced task than gait and that there was a need for more demanding locomotor tests to determine locomotor performance. Although their study was undertaken on patients who had undergone total hip arthroplasty (THA) the arguments for the inclusion of a stair test in the assessment of locomotor ability are similar to those that could be made for TKA. These arguments included the observation that stair activities are frequently reported as limited following surgery and that full locomotor ability is not regained even at 1 year post-surgery.
Although many of these previously described studies have methodological flaws in evaluating validity of the measure (Terwee et al, 2006a), overall their results tend to support the evidence for face validity of timed walking, chair and stair tests in assessing function following TKA. Stratford et al (2003) however explored the content validity of timed tests as compared with the Lower Extremity Functional Scale (LEFS) and concluded that timed performance-based tests failed to represent the complexity of factors relating to ability to function. Although the fast SPW, TUG and timed stair test all showed good reliability, again only moderate correlation ($r < 0.6$) could be found with the patient self-reported measure. Factor analysis revealed that when questions relating to pain and exertion were added to the timed tests, correlations improved, indicating that patients interpret ‘difficulty’ in the self-report measure as having more dimensions than time taken to complete the task alone. These results tended to support the concept that self-reports and performance based measures do not measure the same dimensions of health and therefore adds support to the argument that both should be used in order to evaluate outcomes of TKA fully.

An objective test of ability to undertake functional activities following TKA has been developed by McRoberts. The Dynaport Knee Test (van den Dikkenberg et al., 2002) makes use of accelerometers attached around the subjects trunk and legs. Vertical and sagittal plane accelerations during 29 activities (later reduced to 23 (Mokkink et al., 2005) were monitored by the 6 accelerometers and stored in a data logger worn around the subjects waist. Raw accelerometer data was converted into 30 ‘signal properties’ which included accelerations, angles and temporal parameters of gait. These parameters from test subjects were compared with data from healthy

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3 The Hague, Netherlands
subjects and a score generated based on the difference between the two. All data processing was undertaken using software provided with the system. This novel test provided an objective measure of function and has been shown in preliminary testing to be responsive to change in TKA patients. Reliability in healthy subjects appeared good (all ICC values above 0.7) although confidence intervals were large. No reliability data was reported for subjects with TKA, nor was any information provided about the population on which ‘normal’ parameters were based. A poor correlation was found between the Dynaport Knee Test and the WOMAC pain, stiffness and function scores (Witvrouw et al, 2002). This evidence supported the call for use of performance based measures of outcome along with patient reported measures.

Level of activity is also another aspect of function that has been given only a small amount of attention within the literature. It has been hypothesised that reducing pain and increasing functional ability will increase an individual’s level of activity (de Groot et al., 2008b). Activity levels can be monitored by devices such as pedometers and accelerometers. Although subjects with total joint replacement have been shown to be significantly more active than those with OA of the knee (McClung et al., 2000), de Groot et al (2008) found an increase of only 10 mins (121 mins to 131 mins) in the total amount of time that an individual undertook movement related activity in a 24 hour period. Interestingly, the self-reported activity levels improved by 86% indicating that there was a discrepancy between self-report and actual physical activity levels. Furthermore, although it was hypothesised that reducing pain and increasing functional ability would increase activity levels, linear regression showed that age, BMI and mental health were the only predictors of actual physical
activity levels in those with end-stage OA of the knee (de Groot et al., 2008a). Surprisingly pain was not associated with levels of activity. Self-reported function was not entered into the model as a possible independent variable and thus it is unknown whether functional limitations contribute to levels of activity. Although activity levels increased post-TKA, they remained below that of a healthy control group. Further work is required to determine whether the increases seen were sufficient to see any health benefits.

2.2.4 Outcomes in TKA summary

A wide range of approaches have been used to report function following TKA. Regardless of the approach used, significant improvements in pain and function following TKA have been demonstrated. However, despite this, it seems that function remains significantly worse than control groups (Noble et al, 2005) and worse than population based norms.

The best method for the measurement of function is an unresolved argument. There is good overall agreement that there is little relationship between different measures of function but the subsequent arguments for and against validity of particular instruments appear to be circular. Kennedy et al (2003) for example, questioned the validity of the WOMAC, based on two performance based measures of function. Others (Stratford et al, 2003) however, have questioned the validity of performance based measures based on questionnaires. One possible explanation for the lack of consensus on the evaluation of function following TKA was that none of the studies presented defined what they meant by ‘function’.
2.3 Factors influencing function in Total Knee Arthroplasty

Despite the success of total knee arthroplasty, it is clear from the literature that functional limitations often persist following surgery (Lingard et al, 2004; Noble et al, 2005) with evidence to suggest that up to 30% of patients experience no improvement or even a deterioration in some aspect of their activities of daily living (Dickstein et al, 1998). Furthermore, large-scale studies have reported that up to 20% of patients were either uncertain or dissatisfied with the outcome of their surgery and that functional limitations may contribute to that dissatisfaction (Noble et al, 2006; Robertsson & Dunbar, 2001). In the search for factors that may influence functional outcome, several studies (Fortin et al., 1999; Jones, Voaklander, & Suarez-Almazor, 2003; Lingard et al, 2004) have concluded that the best predictor of post-operative function is pre-operative function. Pre-operative limitations result from pain, soft tissue damage, joint abnormalities and disuse. Surgery addresses the first three of these causes and rehabilitation is intended to address the fourth. Interestingly, Sharma et al (1996) found that after controlling for other significant variables, pre-operative functional status only accounted for 2% of the post-operative function score. These results were only based on a small sample size (n = 47) and used a generic measure of health (SF-36) and thus the conclusions may have not been robust. Other studies (Kreibich et al, 1996; Parent & Moffat, 2002) have shown that the SF-36 to be less responsive to change following TKA than other measures and the use of the SF-36 Role-Physical scale to evaluate post-operative function is questionable. In addition 13 variables were included in the linear regression equation which is greater than the suggested 1 predictor per 10 subjects (Nunnally & Bernstein, 1994). In an example provided by Munro BH (2001), 6 independent
variables required a sample size of 98. It can be seen that a sample size of 47 is far too small for the number of predictors used in the study by Sharma et al (1996).

Thus the questions remains - why do patients have persisting functional limitations? A variety of causes have been suggested which include: habituation of motor patterns, abnormal muscle function, altered proprioception, prosthetic design, decreased range of motion (ROM) and poor pre-operative mental health. It was noted however by (Mizner, Petterson, & Snyder-Mackler, 2005) that the impact of such residual impairments on functional limitations is unclear.

2.3.1 Habituation

Fisher et al. (1997) found that the gait patterns of patients with OA, whose gait patterns were similar to that of TKA and anterior cruciate ligament replacement patients, remained unchanged following rehabilitation. These results, they argue, suggest that “functional adaptations” made as a result of pain, had made patients unresponsive to rehabilitation. Whilst this study does not go as far as proving the theory of habituation, other studies (Andriacchi, Galante, & Fermier, 1982; Benedetti et al, 2003) have also suggested that habituation may be partly to blame for continuing gait deficits.

2.3.2 Muscle Function

In the early stages of recovery following TKA, quadriceps muscle strength of the involved knee has been shown to be significantly worse than the uninvolved knee (Berman, Bosacco, & Israelite, 1991; Lorentzen et al., 1999; Stevens, Mizner, & Snyder-Mackler, 2003). At one year post-op however, the evidence is conflicting.
Berman, Bosacco & Israelite (1991) reported reduced extensor torque at the involved knee compared with the uninvolved knee but flexor torques were nearly equal in both knees. At two years post-op, the extensor torque of the involved knee remained reduced. This study utilised a relatively large sample size at pre-operative testing although by 2 years the follow-up rate was only 52%. A later study (Walsh et al, 1998) found little difference in peak torque between the involved and uninvolved leg in both flexion and extension at 1 year post surgery. Significant differences were found between controls and TKA patients suggesting that function remains reduced in the TKA group even at one year post op (Mizner, Petterson, & Snyder-Mackler, 2005). The results of this study were stratified into gender which makes comparison with other studies difficult but the study was one of the few to compare the results with an age matched control group. Other studies which have considered muscle strength following TKA have either only considered how the operated leg compared with its pre-operative values and have not considered the uninvolved leg (Steiner, Simon, & Pisciotta, 1989). Others (Collopy et al, 1977) have reported results of early attempts at TKA which have been largely superceded with advances in surgical technique and prosthetic design. Although the overall opinion within the literature has been that muscle strength remains reduced following knee arthroplasty there has been no work reported evaluating the impact of reduced strength on function and this remains an area for future research.

One possible explanation for decreased muscle strength may be the reduction in the ability of the individual consciously to utilise the maximal force generating capacity of the muscle. Two studies (Berth, Urbach, & Awiszus, 2002; Mizner, Stevens, & Snyder-Mackler, 2003) both reported significant differences in the voluntary
activation of the quadriceps muscle compared to control groups following TKA. Although Berth, Urbach & Awiszus (2002) reported improvements between pre and post-operative, at 3 years following surgery, the TKA group still had an average voluntary activation deficit of approximately 15% compared to that produced by electrical stimulation. The control group had a deficit of around 9%. Mizner, Stevens and Snyder-Mackler (2003) found a deficit of around 26% compared to the control group but these values are difficult to compare with those reported by Berth, Urbach and Awiszus (2002) as post-operative testing was undertaken at only 3-4 weeks following surgery. As significant differences in pain and function have been found up to 1 year post-op, this may explain the magnitude of the difference these two described studies. In addition the control group used by Mizner, Stevens and Snyder-Mackler (2003) was not well matched – the group were significantly older and had significantly lower BMI. Although it is not known whether either of these factors influence voluntary muscle activation, it makes it even more difficult to compare results.

2.3.3 Proprioception

The results of work on proprioception following TKA have been more conclusive. Several studies (Attfield et al., 1996; Barrett, Cobb, & Bentley, 1991; Warren et al., 1993) that have looked at joint position sense (reproduced on a model) found that error in osteoarthritic knees was reduced following TKA although error remained greater than that in normal controls. These findings were corroborated by Pap et al. (2000) who studied threshold to movement and found replaced knees to be worse than normal controls but also worse than in the unoperated knee. This study was the
only work to consider the impact on outcome (no relationship between joint position error and outcome scores was found) however there were methodological concerns about the evaluation of the clinical outcome (measured by the Knee Society Score - KSS). The KSS has a poorly developed section on function (it only considers distance able to mobilise, use of walking aids and ability to ascend/descend stairs), it is clinician scored and has been shown to be unreliable when evaluated by inexperienced observers (Liow et al., 2000). By contrast, Lattanzio, Chess, & MacDermid (1998) could not find any difference between replaced and unreplaced knees although they used a small sample (n = 20) and studied active reproduction of the angle rather than using a model for angle reproduction.

2.3.4 Prosthetic design

There has been surprisingly little work on the effect of prosthetic design on function following TKA. This may be perhaps due to the numerous designs available. The most commonly reported comparison has been made between cruciate-retaining and cruciate-sacrificing designs. An early study (Andriacchi, Galante, & Fermier, 1982) compared 5 designs for gait characteristics and stair-climbing. The main result was that all patients displayed gait abnormalities (reduced stride length, walking speed, reduced flexion in mid-stance) when compared with normal controls during level walking. The less constrained (cruciate-retaining) designs showed a more normal gait during stair climbing than the more constrained (cruciate-sacrificing) designs. Those with a PCL sacrificing design showed a reduced velocity on stair descent and a reduced range of motion. Andriacchi, Galante and Fermier (1982) postulated that in the absence of a PCL, the forward motion of the femur on the tibia seen during stair
descent, must be resisted by the prosthesis. The study did not attempt to explain why
the prosthetic restraint did not function as well as the ligamentous restraint but
commented that neither the muscles nor secondary ligamentous restraints have
sufficient mechanical advantage. Again the results of this study referred to older
designs of knee replacement and therefore it was difficult to generalise them to more
modern designs of prosthesis. A more recent, prospective study (Victor, Banks, &
Bellemans, 2005) undertook fluoroscopic analysis of a deep lunge and step up/down
activity in 44 patients randomised to receive either the cruciate retaining or cruciate
sacrificing version of the same prosthesis (Genesis II\(^4\)). No significant differences
were found in patient reported measures of outcome (WOMAC, SF-36, Knee Society
Score) although it was concluded that the cruciate substituting (sacrificing) version
of the knee had more ‘natural’ function (contrary to Andriacchi, Galante & Fermier,
1982). This conclusion was based on the observation of the pattern of axial tibial
rotation. Although no differences were found between the knees in overall rotation,
differences were noted in the pattern by which internal tibial rotation was achieved.
In the cruciate retaining knee, anterior sliding of the medial femoral condyle was
observed whereas the same tibial motion was achieved by posterior rollback of the
lateral femoral condyle in the cruciate sacrificing knee. Posterior rollback of the
femoral condyles was commonly seen in normal knee during a deep knee bend
(Komistek et al., 2003) and thus it was concluded that cruciate sacrificing knee more
closely represents normal knee kinematics. The ability to generalise the results of the
study by Victor, Banks & Bellemans (2005) was restricted to one type of prosthesis
although the methodological design reported was appropriate and rigorous. Other

\(^4\) Smith and Nephew, Memphis, Tennessee
studies (Dennis et al., 2003) have observed considerable variation across different types of prosthesis although the anterior sliding of the medial femoral condyle, reported by Victor, Banks & Bellemans (2005) appeared to be a common characteristic of cruciate retaining prostheses. Dennis et al (2003) went on to suggest three potential problems associated with excessive anterior translation, 1) the axis of flexion was also anteriorly translated which consequently reduced the maximum amount of flexion available; 2) the quadriceps moment arm was decreased reducing the efficiency of the extensor mechanism and 3) sliding of the femoral component caused increased wear of the polyethylene tibial tray. Victor, Banks & Bellemans (2005) found no difference in maximum passive flexion between the two groups despite the presence of increased anterior translation in the cruciate-retaining group but these factors perhaps remain an area to be explored in greater detail.

Design of the patellofemoral component has also been shown to influence function (Andriacchi et al., 1997). This retrospective study compared stair-climbing, level walking and chair rising in two groups of patients who had received two different types of knee replacement that included patellar resurfacing. A force plate and a two-camera optoelectronic system captured kinetic and kinematic data. A significant difference in stair-climbing was noted between the two groups. The significantly higher knee flexion moment noted during the stance phase was attributed to a smaller radius of the trochlear notch. Position of the patellar component has also been suggested as having an influence on function (Figgie et al., 1986). A moderate relationship (r = 0.43) was found between patellar height and function evaluated using the Mayo clinic knee score. However over half of variation in patellar height (56%) could be attributed to changes in joint line which were caused mainly by
surgical technique and choice of size of prosthesis. Overall the study lacked methodological rigour which made it difficult to accept the conclusion that patellar position had an effect on function. Without further evidence to support the argument, it must be accepted that this area requires further consideration.

Jacobs et al. (2004) undertook a review of studies which have compared function in mobile and fixed bearing knees and found no evidence of superiority for either of the two types of prostheses. It must be noted however that only two studies could be found and Jacobs et al (2004) considered both to be of low methodological quality.

The difficulty with attempting to evaluate the impact of prosthetic design on function following surgery is the *in vivo* nature of the research. Many confounding variables exist relating to the patient and the influence of the surgical technique adds greater confusion. *In vitro* studies have allowed the mechanical function of the implant to be tested and compared without such confounding variables. DesJardins et al. (2000) described a mechanical wear testing simulator and used it to compare differences in 7 commonly used prostheses. The simulator imposed a simulated gait pattern on the knees and the resulting kinematics compared. Differences between designs were found but these were not statistically analysed or compared with a cadaveric knee joint. The simulator only imposed one constant stiffness value over the range of motion which was recognised as a potential limiting factor and the authors of the paper highlighted this as an area for further research.

The most recent studies have compared ‘high flexion’ prostheses with standard prostheses. High flexion prostheses were developed in response to evidence indicating that the demands of certain occupational, cultural and leisure activities required greater amounts of flexion than that traditionally achieved in patients with
TKA (Sultan et al., 2003). An in-vitro study (Barink et al., 2008) indicated that a high flexion prosthesis demonstrated improved mechanical performance in high flexion compared to normal flexion ranges. So far however the evidence has shown that patients are unable to capitalise on the increased available flexion range and little difference in functional outcome between high flexion and standard designs has been found (Nutton et al., 2007). Nutton et al (2007) concluded that they felt that the prosthetic design had little influence on post-operative function.

2.3.5 Range of Motion (ROM)

The amount of flexion and extension obtained at the knee joint is commonly considered to be a contributing factor in functional deficits following surgery. Patients are frequently set a target of 90° of flexion on discharge from hospital yet there appears to be little evidence to support this target. Rowe et al. (2000) found that out of 11 functional tasks evaluated, only 3 required flexion of less than 90° and only 5 required flexion of less than 100°. This led the study to state that only achieving a maximum flexion of 100° degrees “…would leave the patient barely able to climb stairs or use a chair in a normal manner”. The authors went on to suggest that 110° would be a more appropriate target for rehabilitation. A further study by the same authors (Myles et al, 2001) found that the mean maximum flexion at 18-24 months post-op was only 97° yet patients appeared to be able to undertake all 11 functional tasks albeit with reduced ROM. Although the study clearly found a reduced ROM in patients with TKA, there was no attempt to examine the relationship with patient reported measures of functional ability and thus the study
adds little to the question of why functional deficits frequently occur in the presence of an apparently clinically acceptable result.

Ritter et al. (2008a) undertook a large study to consider the effect of range of motion on functional activities and concluded that the best functional results were achieved with 128°-132° of motion. This study however had some limitations which impacted upon the conclusions that could be drawn from study; 1) this was a retrospective study with data obtained from medical records and 2) functional ability was assessed using the Knee Society Score which considers only stair climbing and walking ability. As has been discussed in section 2.2.3 both patient report and performance based measures are necessary for a complete evaluation of functional ability.

2.3.6 Psychological variables

Several studies have shown that worse functional outcomes in TKA are associated with lower mental health status, for example, depression (Ayers et al., 2005; Faller, Kirschner, & Konig, 2003; Fisher et al, 2007; Fortin et al, 1999; Lingard et al, 2004). Other psychological variables studied have included pain-related fear of movement and self-efficacy. Pain-related fear of movement was found to predict post-surgical functional outcomes although was not as strong a predictor as pain and pre-operative function (Sullivan et al., 2009). Self-efficacy is a measure of a persons’ belief in their ability to undertake tasks and thought to be a better predictor of achievement than a persons capability (Bandura, 1998). Although not extensively studied in those with TKA, there is strong evidence to show that self-efficacy was a strong mediator of function in those with knee OA (Maly, Costigan, & Olney, 2005; Maly, Costigan, & Olney, 2007).
2.3.7 Joint stiffness

Joint stiffness as a mitigating factor in functional limitations has received little attention. Dorr et al (1988) however suggested that TKA patients walked with a stiff legged gait. Other studies have suggested that a moderate relationship may exist between function and patient reported stiffness (Finch et al, 1998; Jogi, Kramer, & Birmingham, 2005). A conference abstract suggested that there was a significant relationship between knee joint stiffness and gait deficits in women with OA (Oatis et al., 1996) however only a very small sample size was used (n = 8) and the reported correlation coefficients varied from $r = 0.252$ (weak relationship) to $r = 0.889$ (strong relationship). The most comprehensive study which has included stiffness found that stiffness was a strong determinant of satisfaction following TKA (Noble et al, 2006). There was no attempt to relate stiffness and function however functional limitations were also found to be a strong predictor of satisfaction. Although the results of this study are interesting, they were based entirely on a subjective questionnaire and as has already been noted, questionnaires on their own provide only a limited evaluation of function.

Gooberman-Hill et al (2009) found that patients with OA of the knee more frequently commented on limitations with stair climbing and stiffness. Although the authors did not go so far as to theorise a relationship between stiffness and activity limitations, they did comment that stairs and stiffness both had a significant impact on patients lives. This study was only undertaken on those with knee OA and not TKA and so it is nor clear to what extent these results can be generalised to a TKA population.
2.4 Joint Stiffness

Although stiffness was recognised by the OMERACT group as an important outcome measure domain in addition to pain and function (Bellamy et al, 1997), no studies have been found that report objective measures of stiffness following TKA. Subjective evaluations (using WOMAC visual analogue scale) however, at one year following TKA, suggest that stiffness remains significantly worse than normal healthy, age-matched controls (Finch et al, 1998). Furthermore, there is some suggestion that patient satisfaction with outcome is related to, amongst other variables, stiffness and therefore may be an important consideration for rehabilitation (Robertsson & Dunbar, 2001).

Other studies have shown that stiffness of the metacarpophalangeal and knee joints was increased in subjects with rheumatoid arthritis (Backlund & Tiselius, 1967; Rasker, Peters, & Boon, 1986; Valle et al., 2006; Wright & Johns, 1960) but little work has been undertaken to explore joint stiffness in osteoarthritis.

Before proceeding to explore stiffness in osteoarthritis and TKA, it was important to define what is meant by the term ‘stiffness’. Some studies have defined stiffness as a simple lack of range of motion and/or the presence of flexion contractures (Bong & Di Cesare, 2004; Kim, Nelson, & Lotke, 2004). One study of patients with rheumatoid arthritis (Rhind, 1987) showed that patients were ambiguous in their definition of stiffness. Words relating to pain, difficulty with movement and sensation were all used to describe stiffness. However these definitions did not match the well-established definition of stiffness in physics which states that stiffness is the “resistance offered by a structure when subjected to external loads” (Panjabi &
White, 2001). The definitions of joint stiffness offered by Haigh et al. (2003) related more clearly to the established generic definition of stiffness:

- Objective joint stiffness – the resistance to passive motion measured as the joint is moved through range.
- Subjective joint stiffness – a perceived resistance (by the subject) to initiation of active motion.

The definition of objective stiffness has been further clarified into elastic stiffness, viscous stiffness, frictional stiffness and plastic stiffness (Table 2.3).

Table 2.3 Definitions of types of stiffness (Wright & Johns, 1960).

<table>
<thead>
<tr>
<th>Type of stiffness</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elastic</td>
<td>Force is a function of deformation</td>
</tr>
<tr>
<td>Viscous</td>
<td>Force is a function of velocity</td>
</tr>
<tr>
<td>Friction</td>
<td>Force is dependent on the coefficient of friction</td>
</tr>
<tr>
<td>Plastic</td>
<td>Stress relaxation and creep occur</td>
</tr>
</tbody>
</table>

There was little evidence that has confirmed whether a relationship exists between objective and subjective measures and therefore caution must be taken to distinguish which entity is being referred to.

2.4.2 Etiology of stiffness in osteoarthritis

Patient reported stiffness is a common symptom of osteoarthritis (Heck et al, 1998). One textbook suggests that typically localised and of short term duration, stiffness in OA is often present on awakening in the morning and after periods of inactivity during the day (Moskowitz, 1993). Objective stiffness has been shown to be
increased in patients with OA (Oatis et al., 1998), however these studies were based on small samples with a wide age range (33-64 years) and these results must be viewed cautiously.

The causes of joint stiffness in osteoarthritis are unclear. Wright (1973) theorised that the stiffness of osteoarthritic patients is due to articular gelling but did not provide evidence to support this theory. A general text on Arthritis (Moskowitz, 1993) appears to consider articular gelling as a separate entity, describing the stiffness in OA as of short duration (lasting < 15mins) and articular gelling as a "transient stiffness lasting for only for several flexion-extension cycles". It was only later, that a study showed that articular surfaces from diseased joints were more likely to bond together than normal bovine cartilage (Hills & Thomas, 1998). It was suggested that surface-active phospholipids (SAPL) could be responsible and that SAPL is deficient in the articular surfaces of hips and knees replaced at surgery. However this in-vitro study compared diseased human with healthy bovine cartilage and although articular gelling was clearly demonstrated, the study could not definitively conclude that articular gelling was the cause of stiffness in OA.

Other studies have suggested that joint stiffness in OA was due to stiffness of the surrounding soft tissues. Fishkin et al. (2002) studied the effect of OA on stiffness in the medial (MCL) and lateral collateral (LCL) ligaments in both a group of patients undergoing TKA (n = 10), a group of fresh cadavers (n = 10) with evidence of osteoarthritis in the knee joints and a control group of cadavers (n = 10). Knee arthroplasty was performed on all groups and the flexion and extension gaps on both the medial and lateral side evaluated. Load and elongation of the collateral ligaments was recorded and the subsequent slope of the curve calculated. Analyses found that
there was significant stiffening of both the medial and lateral compartments of the knee in both the patients and OA cadaveric knees. They concluded that OA could significantly affect the ligaments of the knee joint.

Thus a variety of mechanical factors have been suggested that may contribute to knee joint stiffness in osteoarthritis. Suggestions have included the ligaments and capsule, muscle shortening, intrarticular adhesions, scar tissue (Herbert, 1993; Wright & Johns, 1960), osteophyte and cyst formation (Levine, 1988) but little evidence has been offered to support these suggestions.

A theoretical relationship between joint stiffness and muscle strength has been proposed (Lung, Hartsell, & Vandervoort, 1996) (Figure 2.1). It was suggested that joint stiffness could result in joint contractures, which in turn, may effect a change in the resting length of the muscles. The resulting change in levers causes a change in muscle torque output and an eventual muscle imbalance. The muscles become unable to move the joint through its full available range of motion, resulting in further restriction. This model could account for changes in stiffness around the OA knee and subsequently the replaced knee, however, Lung, Hartsell, & Vandervoort (1996) presented no evidence in support of this hypothesis and a review of the literature has not revealed any subsequent work.
Early work (Wright & Johns, 1960) found that stiffness of the metacarpophalangeal joint increased with age although the conclusions were based on a sample size of 3 and no statistical inference was made. A later study (Barnett & Cobbold, 1968) with much larger numbers (n = 111) agreed with these findings however both these early studies examined stiffness only in the finger joints. Ankle joint stiffness has also been reported in several studies and studies of the influence of age on ankle joint stiffness has proven inconclusive. Chesworth & Vandervoort (1989) found no significant difference in passive ankle joint stiffness whereas a later study of stiffness...
at the ankle joint found stiffness actually decreased with age (Gajdosik, Van Der Linden, & Williams, 1999). Osteoarthritis principally affects the older generations, with the majority of sufferers being over the age of 50 (Altman et al., 1986). Thus the stiffness felt in osteoarthritis could possibly be due to age related changes in the soft tissues rather than specifically joint disease. There has been some suggestion that perceived stiffness is not only due to peripheral mechanisms but may also be modulated by the central nervous system. A small sample study of patients with rheumatoid arthritis (RA) who had undergone unilateral amputation showed that perceived stiffness remained in the phantom limb (Haigh et al., 2003). It was suggested that neuroplastic changes within the brain (similar to those which have been implicated in chronic pain) may be responsible. The study claimed that this was evidence that there is no relationship between objective and subjective measures of stiffness although the small sample (N = 3) lacked statistical power to infer the findings. However, these results agreed with an early study (Helliwell, Howe, & Wright, 1988) who reported no difference in mechanical stiffness of the metacarpophalangeal joint between subjects with RA and healthy controls and concluded that these results “cast doubt” on subjective stiffness as an indicator of disease activity. All the participants with RA were reported to have complained of stiffness but no subjective assessments of stiffness were taken on either RA or control subjects. A later study (Helliwell, 1997) found that some RA patients were unable to detect changes in objective metacarpophalangeal joint stiffness following a corticosteroid joint injection. The authors discussed 4 possible explanations which included 1) the subjective and objective measures, measure different things, 2) patients’ perceptions of stiffness may have been biased by what they thought the
clinician wanted to hear, 3) there may have been a threshold effect for objective stiffness under which stiffness was not perceptible, 4) people may have differed in their sensitivity to stiffness. These explanations however were only hypothesised and no further work has been undertaken to provide evidence to support or reject the theory.

2.4.3 Aetiology of stiffness following total knee arthroplasty

Stiffness following TKA is not well studied. Subjective evaluation has suggested that although perceived stiffness generally reduces, it can remain a problem for a proportion of patients (Heck et al, 1998; Noble et al, 2006). Vince & Eissmann (1994) suggested that a number of factors may contribute, these included: reflex sympathetic dystrophy (RSD), neuromuscular disorders and surgical technique.

2.4.3.1 Extra-articular causes

RSD is thought to be relatively uncommon (0.8% of patients) after TKA (Katz & Hungerford, 1987) although its diagnosis can be difficult. Pain is always present, frequently severe and persistent. Other acute symptoms include oedema, redness and heat - all symptoms common in the early post-operative phase of a TKA. As the condition progresses, range of motion is decreased and the skin becomes cold and glossy. If the condition persists, contractures form and the oedema hardens further contributing to sensation of stiffness (Vince & Eissmann, 1994).

Neuromuscular disorders such as Parkinsons disease can also contribute to a stiff TKA. The mean age for a TKA in Scotland is 70 (Scottish Arthroplasty Project, 2004), similar to the age range in which Parkinsons is most common (Koller, 1987).
Muscle rigidity is a phenomenon associated with Parkinson disease and is thought to be associated with exaggerated tonic stretch reflexes. It is thought that up to 1% of the population > 65 years of age are affected by the disease. Thus the possibility of neuromuscular disorders as a cause of stiffness should be considered.

2.4.3.2 Intra-articular causes

Stiffness has also been claimed to be associated with “arthrofibrosis” (Sharkey et al., 2002). However this study was based on the analysis of intra-operative findings at revision surgery and it was not stated how many surgeons participated in the study and on what basis they classified tissues as having undergone “arthrofibrosis”. It should also be noted that none of these revisions had undergone surgery specifically for stiffness. Finally, and most importantly, stiffness was not measured (either subjectively or objectively) and therefore the claim for an association between stiffness and “arthrofibrosis” was not supported with valid evidence.

2.4.3.3 Surgical technique

One of the goals of bone resection during TKA surgery is to site the joint line of the prosthesis at the same level as the original joint line (Miller, 2004). Shifting the joint line distally has been reported to cause stiffness in mid-range (Martin & Whiteside, 1990). This study however was performed on cadaveric specimens and therefore the clinical implications of these effects could not be evaluated. Sidles et al. (1986) made similar conclusions based on a 3-D mathematical model of the knee however their study also suffers from the limitations of generalisation to a patient population. One study that considered the effect of changing the joint line on patient population Figgie et al (1986) claimed that the quantitative knee score had a significant
correlation with change in joint line however a closer examination of the results shows a correlation coefficient of only -0.42 with a p-value of < 0.0001. A value of ±0.42 is considered to show only a low strength of relationship (Munro BH, 2001) and the p-value only relates to the probability that the relationship occurred by chance. The Mayo Clinic knee score was used which only assesses function, not stiffness, and which is an unvalidated score (no papers could be found describing the validation of this score). A further limitation is that it based on the surgeons’ interpretation of the patients ability rather than patient report.

Choice of prosthesis is also thought to influence stiffness of the replaced knee. Normal joint kinematics require both the anterior cruciate ligament (ACL) and posterior cruciate ligament (PCL). The ACL is usually destroyed by the disease process of OA however the PCL usually remains functional (Aglietti & Baldini, 2000). Many prostheses offer the option to retain or to sacrifice the PCL. It is thought that resection of the PCL can lead to an increase in the flexion gap (Dorr & Boiardo, 1986; Sierra & Berry, 2008) although contradictory evidence was offered by Baldini et al. (2004). Sierra and Berry (2008) stated that where a PCL retaining prosthesis is used, less bone should be removed from the distal femur as removing too much will cause a flexion/extension gap imbalance that can only be resolved by distal femoral augmentation. A larger polyethylene insert could account for the extension space but would cause ‘overstuffing’ of the flexion gap. They went on to describe how more bone should be removed in the case of a PCL sacrificing design to avoid making the flexion gap larger than then extension gap. Where this occurs, filling the flexion gap with a larger polyethylene insert will result in tightness in extension. The comments however offered by Sierra and Berry (2008) are not
supported by direct empirical evidence based on observation from patient populations.

In relation to restoration of the joint line, the size of the prosthetic components is also crucial. When components that are too large are implanted, the joint is said to be ‘overstuffed’. Overstuffing can occur for several reasons (Bong & Di Cesare, 2004). If too much bone is resected from the femur, a larger femoral component has to be inserted to account for gap that occurs whilst the knee is extended. However this results in tightness when the knee is subsequently flexed. Occasionally, a larger femoral component is inserted if the joint falls between sizes on the sizing gauge and this then also can result in stiffness in flexion. If the patella is also to be replaced then ‘overstuffing’ of the patellofemoral joint results in tightness of the extensor mechanism and subsequent stiffness.

In all the above studies of surgical technique, reference was made to stiffness without defining what was meant by stiffness. No studies have been undertaken to consider the effect of surgical technique on joint stiffness using either subject or objective measures of stiffness taken from a patient population and thus further work in this area is needed.

Knee stiffness has been referred to in terms of reduced ROM following TKA (Dorr et al, 1988; Benedetti et al, 2003). Noting decreased flexion in loading and an overall decreased flexion arc during gait, Dorr et al (1988) briefly postulated that this could be due to two causes 1) increased joint friction in the prosthetic joint and, 2) habituation of gait. Benedetti et al (2003) also claimed that the maximal flexion during the loading response was significantly different but no post-hoc analyses between 3 post-operative time points (6, 12 and 24 months) was undertaken.
following the repeated measures ANOVA and therefore it is not clear where differences lie. Values for a control group were reported but no statistical analysis was undertaken for this group. The descriptive statistics however suggest that all post-operative values are decreased compared to the controls. Both studies referred to these gait characteristics as a “stiff knee pattern” which appeared to be associated with increased muscle activity during stance.

2.4.4 Measurement of joint stiffness

Prior to the 1960's, joint stiffness was primarily evaluated using subjective methods. In the early 1960's attempts began to develop a method for the objective measure of stiffness. One of the problems with the objective measurement of stiffness lies in the interpretation of what the term 'stiffness' actually means. In Physics, stiffness has been defined as the relationship between the stress (the deforming force) and the strain (the resulting elastic deformation) of a material (Latash & Zatsiorsky, 1993) (Figure 2.2).

![Stress/strain graph](image)

Figure 2.2 Stress/strain graph

Latash and Zatsiorsky (1993) commented that when considering ideal materials (such as a spring) this poses little problem but when studied in a biomechanical
context, it becomes more complicated. The concept of stiffness (as defined in Physics) can only be applied to certain materials that deform under the influence of an external force. If this external force is absent, the material should maintain a constant shape. Latash & Zatsiorsky (1993) maintained that muscles do not adhere to these principles and furthermore, the complex nature of joints, which consist of several types of materials, makes the measurement of stiffness difficult. Nevertheless, they concluded that this does not mean that joint stiffness should not be studied. They suggested that studies are confined to analyses of single joints, should be clear about which of the joint components is being studied, should state the extent to which the results are related to the properties of the system and to what extent they reflect the experimental procedure.

2.4.4.1 Subjective Measurement of Stiffness

Previous studies have utilised questionnaires (such as the WOMAC) and visual analogue scales in order to elicit patient reported measures of stiffness. The validation of such approaches however has assumed that patients are able to determine the difference between stiffness (Bellamy et al, 1988). The Cyriax approach to joint testing supposes that resistance to motion can be detected by an examiner undertaking passive motion of the joint (Hayes, Petersen, & Falconer, 1994) however the inter-rater reliability of these tests has been shown to be low casting doubt upon validity of the tests.

2.4.4.2 Passive Resistance to Motion Method

Wright and Johns published early work on the quantification of joint stiffness. In 1960, they first described apparatus for measuring stiffness at the second
metacarpophalangeal joint (Wright & Johns, 1960) and in 1961 described joint stiffness in normal subject and patients with connective tissue disease (Wright & Johns, 1961). A sinusoidal motion was imposed on a finger holder by a cable driven by a variable speed motor. The amplitude of rotational displacement, velocity and the torque were recorded. It was claimed that the type of stiffness (elastic, plastic, viscous, inertial and coulomb) could be determined from the torque-displacement and velocity-displacement curves. This study was one of the first to describe joint stiffness in precise physical terms and to differentiate the different parameters contributing to total stiffness. It was discovered that although elastic stiffness was the major contributor, the trace displayed hysteresis. This was thought to be due to viscous and plastic effects. Although the study made several conclusions, the work is lacking in several areas. It was stated in the study that no electromyographic activity was detected but the method used to determine this was not described. Although the sample size was moderate, little information was provided about the subjects. Stiffness was stated to increase with age but the distribution of ages was not provided and no statistical analysis was offered. In addition temperature and oedema were artificially induced. Intramuscular needles were used to monitor the temperature of the forearm muscles but even using this method, the intra-articular temperature of the joints could not be reliably recorded. Local oedema was induced by an injection of saline into the capsular region. Although this enabled the degree of oedema to be standardised, joint injections can be painful and it was not clear whether pain may have contributed to the resulting stiffness. Despite these caveats this study has provided a useful basis for the development of the passive resistance to motion method of measuring joint stiffness.
A similar method for the measurement of passive resistance was later applied to the knee joint (Such, 1971; Such et al., 1975). Seventy subjects, from a range of ages (49 males and 21 females), were tested. None had history of joint pathology. The lower limb was passively moved through flexion and extension at a velocity of 0.078 rad/s. The results were reported as 'dissipated energy' which was not clearly explained. The torque-displacement curves appeared to show hysteresis (as also described by Wright and Johns, 1961) and the area inside the curve was stated as total energy loss (which was presumably the reported 'dissipated energy'). The slope of the line bisecting the torque-displacement curve was described as elastic stiffness however stiffness was also referred to as peak-to-peak torque and reported as Nm. These values were described between 3Nm and 6Nm. Overall it is difficult to compare and contrast the results of this study with earlier work due to the non-standard reporting of the results and a lack of statistical evaluation. The work of Such et al (1975) was further developed by Heerkens (1985) using a modified version of the knee arthrograph previously described by Such et al (1975). The modified arthrograph had a new moment transducer and an electromagnetic clutch but neither study evaluated validity or the reliability of the system so it is difficult to determine, what difference the changes to the arthrograph made to the results. In both studies, a counterweight was used to balance the moment created by the mass of the shank and foot. The position of the counterweight was determined empirically in the study by Such et al (1975) by manually moving the counterweight until the system was balanced. A major improvement on this in the study by Heerkens (1985) was that the value of the moment required to balance the system was calculated mathematically using anthropometric data. In addition Heerkens (1985) clearly described the data
processing and statistical techniques used to evaluate the data. Engin (1985) described the passive resistance to motion in 3 male subjects. The methodology was not completely described - the age of the subjects, the velocity of movement and whether EMG was used to determine whether the agonist and antagonist muscles remained inactive during the passive movement, all of which limit the ability to compare these results with others, however similar values to other studies were obtained. The maximum passive resistive moment at flexion and extension was ~85Nm and ~65Nm respectively. Between 20° and 70° of flexion, the resistive moment was approximately 20N (these values were extracted from graphical representation of the results and are therefore approximate).

The effect of the passive resistance to motion has also been described as the passive elastic moment. Mansour & Audu (1986) studied this at the knee and considered the effect on gait. Subjects were tested in side lying (compared to sitting in the study by Such et al, 1975) in order to remove the effects of gravity. Again the knee was passively flexed and extended using slow velocities (approximately 0.20 rads⁻¹) to minimise the influence of the viscous response. Unfortunately it is difficult to generalise these findings to a wider population as only four subjects aged 23-30 were used and the passive elastic moment was compared to the total knee moment during gait using previously published data (gait data was not collected for the four study subjects). The results showed that the resistive torque at full knee flexion varied with the degree of hip flexion. Flexion of the hip caused the hamstrings to lengthen and the rectus femoris to shorten. At knee extension this had little effect on knee stiffness but increasing hip flexion caused generally smaller passive knee moment throughout knee flexion. The values for the passive knee moment ranged from 3.5Nm to
52.9Nm. The study was interesting in its conclusion that the passive moment at the knee was of the same magnitude (and some cases greater than) the total moment generated during normal gait. Using Newtons Laws, it is not possible for the passive resistive moment to exceed the total moments generated during gait and the body to remain in motion. If the passive resistive moment exceed the overall moment, the body would not be able to move. The study recognised that using gait data from a different sample than the study population introduced limitations that may have attributed for this inconsistency. Other suggestions for the inconsistencies were that some muscle activity was present (muscle activity was not recorded during the tests) or that the sequence of angles through which the knee was rotated was not the same as those displayed during gait. Similar findings were later reported (Riener & Edrich, 1999) although subjects were again limited to a small number, limited in age range. McFaull & Lamontagne (1993) used a similar methodology and found that the values for the passive elastic moment in the midrange of knee flexion were very small (< 5Nm) whilst maximum values ranged from 22Nm at full extension to 86Nm at full flexion. However again, the study sample was very small (n = 17) and limited to young males. Again this study described using low angular velocities (0.20 rads\(^{-1}\)) in order to minimise the viscous response. Although performing stiffness and viscosity tests at low speeds may help to account for these confounding variables, low velocities are not necessarily representative of normal movement. Angular velocities during sit-to-stand of healthy subjects over the age of 60 years has been reported as 2.78 rad/s (Schenkman, Riley, & Pieper, 1996) and 2.15 rad/s (Jevsevar et al, 1993). During gait, angular velocities ranged from 6.54 rad/s in swing phase to 1.68 rad/s during stance phase (Jevsevar et al, 1993). Values for arthroplasty patients, although
significantly lower than controls (5.59 rad/s during swing phase extension), remained much higher than the velocities at which stiffness has been previously measured. Similar velocities were reported for patients with osteoarthritis (Messier, 1994). Thus by failing to test joints within their normal range of angular velocity and removing the contribution of the viscous response, previous studies may have underestimated the total stiffness response. This area thus requires further study in order to appreciate the various physical properties that contribute to stiffness of the knee joint in both normal and diseased joints.

Klinge et al. (1997) utilised a different methodology to study stiffness at the knee joint during knee extension. Twelve subjects undertook a strength training program on one leg and a strength and flexibility program on the other leg. Ten subjects acted as controls. The passive resistance to motion during knee extension was measured by an isokinetic dynamometer (KinCom\textsuperscript{5}). Stiffness was calculated from the slope of the resulting torque-displacement curve. Hip position was not stated although subject position was standardised. The knee was passively extended by the machine at 0.087 rad/s (5 deg/s) to a predetermined stop at the point where a stretch in the hamstrings muscle could be felt. Muscle activity in the hamstrings group was monitored using surface EMG. This was the only study to consider the test-retest reliability of the measure. However, reliability was assessed using Pearson correlation coefficients which are inappropriate for the evaluation of test-retest reliability (Pearson correlation coefficients are an indication of association, not a measure of agreement). Extrapolating data from the graphs presented, stiffness was shown to be measured in

\textsuperscript{5} Chattecx Corporation, Hixson, Tennessee
the range of ~20Nm/rad to ~58Nm/rad. Stiffness increased following strength training and the addition of flexibility exercises did not alter these findings.

Other studies have described the use of the passive resistance to motion method to describe stiffness in the hip joint (Yoon & Mansour, 1982) and the ankle (Siegler, Moskowitz, & Freedman, 1984; Chesworth & Vandervoort, 1988; Chesworth & Vandervoort, 1989; Chesworth & Vandervoort, 1995; Gajdosik, Van Der Linden, & Williams, 1999; Salsich, Brown, & Mueller, 2000; Lamontagne, Malouin, & Richards, 2000; Moseley, Crosbie, & Adams, 2001).

The effect of the internal passive moment on gait was studied by Yoon and Mansour (1982) in the hip and by Siegler and Moskowitz (1984) in the ankle. It was found that the hip passive elastic moment had a significant contribution to the total internal moment whereas in normal ankles, stiffness played a negligible part. No studies have been done on pathological hips but the one ankle with pathology (a hemiparetic adult with a mild equinus deformity) studied by Siegler and Moskowitz (1984) showed that 21% of the total internal moment was contributed by the passive resistance to motion. This agreed with a larger study by Lamontagne, Malouin & Richards (2000) who studied the contribution of passive stiffness to the total ankle plantarflexor moment during gait in 14 hemiparetic subjects. Stiffness was found to contribute a mean of 16.8% (range 2.9% to 49.6%) to the total plantarflexor moment. Few of the other studies have considered the effect of pathology on stiffness or the effect of stiffness on functional activities of daily living. Chesworth and Vandervoort (1995) looked at stiffness in ankle fractures. Only severely fractured ankles (those that required casting) showed significantly greater passive elastic stiffness. However the clinical significance of these findings was not reported. Salsich, Brown & Mueller
(2000) noted that in subjects with diabetic peripheral neuropathy there was a significant relationship between plantarflexor strength and passive plantarflexor muscle stiffness although no such relationship was found in healthy controls. Both Salsich, Brown & Mueller (2000) and Lamontagne, Malouin & Richards (2000) concluded that in subjects with decreased strength, stiffness may provide a useful contribution to the total torque output and that methods to decrease ankle stiffness should be used cautiously.

Many of the studies described previously have used strain gauges incorporated into a specially designed arthrograph. These systems are not commercially available and little is known about their reliability and validity. Some studies used a commercially available isokinetic dynamometer in passive mode (such as the Kin-Com$^5$) however these systems are expensive, lack portability and require a dedicated room space. Furthermore, some studies of the reliability and validity of isokinetic dynamometers have reported measurements errors such as control of lever arm velocity (Drouin et al., 2004; Taylor et al., 1991), inertial effects (Iossifidou & Baltzopoulos, 2000) and gravitational moment correction (Kellis & Baltzopoulos, 1996). Although using motors to standardise the velocity of movement may increase the reliability results obtained, Wood et al. (2005) commented that motor controlled movements cannot detect physical movement constraints i.e. contractures, and as such can pose a health and safety concern. Furthermore, errors in control of lever arm velocity would negate any advantages offered by using motors to control movement.

One assumption made in many of the studies that have used an arthrograph to measure knee joint stiffness (Heerkens, 1985; McFaull & Lamontagne, 1993; Such, 1971) was that the centre of rotation of the knee joint was accurately aligned and
remained aligned with the centre of rotation of the measurement rig throughout joint motion. Studies of the knee have generally used the lateral femoral epicondyle to estimate the transepicondylar axis which has been shown to approximate the flexion/extension axis of rotation (Churchill et al., 1998; Most et al., 2004).

A slightly different application of the passive resistance to motion method has been in the assessment of joint stability. Knee arthrometers (such as the KT-1000) have been frequently used to evaluate joint laxity following ACL rupture/reconstruction (Sernert et al., 2004; Tyler et al., 1999). These arthrometers applied a shear force to the tibio-femoral joint and were used to assess stiffness of the ACL. Borsa, Sauers, & Herling (2000) used a similar approach to assess the shoulder joint and claimed to have been able to assess joint laxity and joint stiffness. Laxity was assessed as the amount of movement at the glenohumeral joint at set amounts of force, stiffness was calculated from the slope of the force-displacement curve. Resistance to motion in these situations is primarily provided by the ligaments and joint capsule, the muscles being at their resting length. Although these types of assessment of laxity and stiffness are useful in the evaluation of joint stability, they do not assess the resistance to normal physiological motion at the joint.

The passive resistance to motion (PRM) method measures stiffness using the traditional definition of stiffness as already described by Latash and Zatsiorsky (1993). The force required to deform the body (stress) and the subsequent deformation (strain) have been measured and their relationship evaluated. The studies described previously (Mansour & Audu, 1986; McFaull & Lamontagne, 1998; Such et al, 1975; Wright & Johns, 1960) all used a force transducer to measure the deforming force and a potentiometer to measure the strain although little
description is made of the force transducers used and the reliability of these. Wood et al (2005) commented that in addition to the stiffness values calculated from the slope of the line, it may be useful to measure ‘threshold’ values of angles and torque where stiffness can be seen to significantly increase. There is considerable variation in the literature in relation to the values reported. Some studies report the slope of the line (true stiffness), others report maximal resistive torque.

Of the studies described previously, few have given consideration to the effects of inertia on the results. As a proportion of the torque measured is required to accelerate/decelerate the limb, limb inertia must be accounted for. Inertial stiffness is a function of force and acceleration. Newtonian mechanics state that:

$$\text{Force} = \text{mass} \times \text{acceleration}$$

(Netwons Second Law)(LeVeau, 1991)

Wright and Johns (1961) considered the inertial parameters of the system by substituting the finger with a cylinder of the same configuration and mass. They found that at slow accelerations (below 56 rads$^{-2}$), inertial torque was minimal. Such et al (1975) also commented on inertia but simply claimed that a velocity of 0.078rs$^{-1}$ was sufficient to reduce the inertial effects of the leg. No evidence was provided to support this claim. Mansour and Audu (1986) failed to comment on the inertial properties of the leg but they used a velocity similar to that of McFaull and Lamontagne (1993, 1998). McFaull and Lamontagne (1998) considered the effect of inertia on viscous parameters but only stated that inertia was often taken into account in biomechanical models and did not specify how inertia might have influenced the results of their model.
Calculation of the inertial effects requires calculation of body segment parameters in order to determine the mass of the lower leg and foot (M_{l&f}), length of the lower leg and foot (L_{l&f}), position of the centre of mass (CoM_{l&f}) and the radius of gyration of the lower leg and foot (k_{l&f}). There are several frequently cited papers reporting anthropometrical data for the calculation of these body segment parameters (Clauser, McConville, & Young, 1969; Dempster, 1955; Drillis, Contini, & Bluestein, 1966) however there are several problems associated with using these published values. Cadaveric studies (Clarys & Marfell-Jones, 1986; Clauser, McConville, & Young, 1969; Dempster, 1955) have been small in sample size and not necessarily representative of the study population in terms of age, body mass and stature. Drillis Contini & Bluestein (1966) used live subjects which provided a larger study sample however these subjects were volunteer students from New York University, whom it could be argued, were a very different population from those undergoing total knee arthroplasty who tend to be elderly and slightly overweight.

In an attempt to address the issues about using cadavers that were different in size and stature to elderly males and females, (Jensen & Fletcher, 1994) and (Pavol, Owings, & Grabiner, 2002) used mathematical techniques to predict body segment parameter data and compared this with previously published work. The study by Jensen and Fletcher (1994) used 12 females (mean age 67.4 yrs) and 7 males (mean age 69.5 yrs) and was found to be consistent with previously reported literature (Dempster, 1955). Pavol, Owings and Grabiner (2002) reported a method of calculating the mass and location of centre of mass using 32 body measurements and compared their results with those of Jensen and Fletcher (1994). Subjects undergoing total knee arthroplasty within the region of Lothian, are typically aged 72 (range 47 –
years and have a BMI of 28.6 (range 21.0 – 40.6) (Lane, Lingard, & Howie, 2004) thus it appears appropriate to use the calculations of Dempster which have been corroborated by more recent studies (Jensen and Fletcher, 1994; Pavol, 2002) to describe the anthropometrical measurements of a population of elderly patients undergoing TKA within Lothian Region.

It has already been mentioned that the passive resistance to motion method relies on the assumption that the motion remains truly passive. Many of the previous studies on stiffness have used surface electromyography to monitor the activity of the thigh muscles during testing but few have provided much detail of the testing procedure. Basmajian & DeLuca (1985) suggested the following set up:

- Interdetection surface spacing 1cm
- Input impedance > $10^{12}$ Ohms
- Common-mode rejection ratio > 100dB
- Bandwidth 20-500Hz.

Many of the studies that have described surface EMG in stiffness studies (Gajdosik, Van Der Linden, & Williams, 1999; Klinge et al, 1997; Lamontagne, Malouin, & Richards, 1997; McNair et al., 2002) have utilised similar set-ups but there is scant evidence of where electrodes were placed or how the resulting EMG data were processed. Basmajian and DeLuca (1985) suggested that the detection electrode is placed halfway between the centre of the innervation zone and the further tendon. The purpose of using EMG is monitor muscle activity to ensure that the motion is truly passive. However, the level of electrical activity at which quadriceps is considered not to be purely passive is debated. Blackburn et al. (2004b) simply instructed subjects to keep activity at a resting level whilst monitoring activity on an
oscilloscope. Trials which showed activity above the baseline (relaxed) were discarded.

2.4.4.3 Pendulum Method

In 1951, Wartenberg (1951) used the concept of the knee as a damped spring to describe stiffness around the knee joint due to spasticity. Wartenburgs Pendulum test, as it has become known, evaluates the ability of the knee to swing freely, through the measurement of the pattern of oscillation. In 1993, Oatis evaluated the method in 96 healthy adults. It was concluded that the method was reliable and simple and quick measure of stiffness in the knee joint. Studies using the method have shown significant differences between controls and patients with arthropathy (Oatis et al., 1995; Valle et al, 2006). A further study by the same author (Oatis et al, 1996) reported positive correlations of stiffness with double limb support ($r = 0.542 - 0.859$) and stance times ($r = 0.252 - 0.454$). Negative correlations were found between step length ($r = -0.478 - -0.704$) and velocity ($-0.31 - -0.374$). The two studies however have only been reported as conference abstracts and as such are difficult to evaluate with regards the methodological quality. The sample size was small in both cases ($n = 19$ and $n = 8$ respectively) and the correlation coefficients reported in relation to gait were variable and did not suggest strong relationships in many cases. McNair, Wood, & Marshall (1992) however reported stronger relationships between patient reported measures of function and stiffness in ACL-deficient patients. Several authors have proposed that the hamstrings contribute to the stability of the knee joint (Blackburn et al., 2004a; McNair, Wood, & Marshall, 1992) and therefore suggested that stiffness of hamstrings may act as a protective mechanism. Hamstra-Wright et al. (2005) went on to use the technique in the
evaluation of joint stiffness in young adults (ages 18-35) with patellofemoral pain syndrome (PFPS). Interestingly a relationship between subject-reported stiffness (assessed using a visual analogue scale) and mechanical stiffness was found. There was no significant difference between mechanical stiffness between PFPS subjects and controls although there were significant differences in self-reported stiffness. Significant correlations between pain and self-reported stiffness led the authors to suggest that individuals with PFPS were misinterpreting pain as stiffness – a similar conclusion to that made by previous researchers (Helliwell, Howe & Wright, 1988) in their study of metacarpophalangeal stiffness in rheumatoid arthritis. Although the technique was reportedly quick and simple it has several potential limitations to its use. Firstly, the technique relied on the subject completely relaxing the quadriceps muscle in order to allow the limb to swing freely and unsupported. Those using the method (Brown et al., 1988; Oatis, 1993) reported no problems in gaining satisfactory tests in healthy subjects but neither study assessed its use in painful knees. Although Hamstra-Wright (2005) did use the method in painful knees, they admitted that the number of trials required to obtain 3 acceptable oscillations was not recorded. Secondly, it was limited in the amount of information it could yield. The stiffness and damping coefficients did not allow the researcher to determine the source of the stiffness or indeed the type of stiffness displayed (elastic, viscous, inertia, friction or plastic). It also did not allow the full range of motion of the knee to be evaluated nor allow angle specific changes in joint stiffness to be assessed. Furthermore, the test could only calculate stiffness at a given speed which was determined by the natural frequency of the leg (Wood et al, 2005). Latash and Zatsiorsky (1993) criticised the damped pendulum approach claiming that this theory
was based on the assumptions that 1) the system was unidimensional and massless 2) the inertia was concentrated at one end and 3) that the coefficient of viscosity, the stiffness and inertia were time (and therefore length and velocity) independent. They went on to state that these assumptions cannot hold true for most biological systems, particularly the assumptions about time dependency.

2.4.4.4 Dynamic Joint Stiffness

Mansour & Audu (1986) attempted to place the passive elastic moment into functional context by comparing their results with published data on the external moments during gait. Other authors however have attempted to quantify the resistance of the joint to motion during normal ambulation using kinetic and kinematic data (Davis & DeLuca, 1996). Davis & DeLuca (1996) performed a retrospective analysis of 28 children and evaluated the relationship between the ankle moment and plantar-dorsiflexion ROM during gait. During the second rocker phase of gait, the mean stiffness was estimated to be 0.058 (Nm/kg)/deg. This method was limited in that it could only estimate stiffness whilst the limb was in contact with the forceplate. Maximum flexion at the knee during gait tends to occur during the swing phase and therefore this tended to limit the usefulness the force plate as a method of measurement around the knee. In addition, the differing units of measurement made it difficult to compare this analysis with previously published work on adults.

2.4.5 Factors affecting joint stiffness

Joint stiffness has been shown to be extremely variable between subjects and this may be attributable to a variety of factors.
2.4.5.1 Segmental parameters

In their discussion, Mcfaull & Lamontagne (1998) suggested that the large degree of variability noted in their subjects may have been due to anthropometrical variance yet they failed to measure such variables and thus the contribution could not be evaluated. Studies of the finger (Helliwell, 1995; Helliwell, Howe, & Wright, 1988) have shown that stiffness of the MCP joints is influenced by finger circumference and forearm muscle bulk. Studies of the knee (Heerkens, 1985; Such et al, 1975) have also noted an increase in resistance to passive motion with increasing anthropometrical measures. Both these studies normalised their data for thigh segment mass but neither study attempted to evaluate the level of the contribution of thigh segment mass to joint stiffness using statistical methods. Thus it would appear that segment mass may be a factor, but the degree to which stiffness values are influenced is not known.

2.4.5.2 Gender

Some studies have claimed that gender differences exist in joint stiffness (Bryant & Cooke, 1988; Heerkens, 1985; Oatis, 1993; Such et al, 1975; Wright & Johns, 1961). Such et al (1975) and Heerkens (1985) both adjusted their data for variance due to anthropometric differences and although differences between genders were reduced by this correction, differences were still found to exist. Blackburn et al (2004b) however found that no gender differences were present when passive knee flexor stiffness was normalised for thigh segment mass. The reasons for these discrepancies were unclear however it may be of note that the two earlier studies (Such et al, 1975 and Heerkens, 1985) both took direct circumferential measurements of their subjects yet Blackburn et al (2004b) used the equations of Dempster (1955) to estimate thigh
segment mass. Pavol, Owings, & Grabiner (2002) showed that although thigh circumference was a significant factor in the prediction of thigh segment mass, other factors such as segment length and body mass were required for an accurate prediction in older adults.

Differences in gender between the viscoelastic properties of the tissues has been suggested as a contributory factor (Lung, Hartsell, & Vandervoort, 1996) and has been supported by others (Kubo, Kanehisa, & Fukunaga, 2003).

2.4.5.3 Age

A variety of studies have reported increasing joint stiffness increases with increasing age (Chesworth & Vandervoort, 1989; Oatis, 1988; Vandervoort et al., 1992; Wright & Johns, 1960). The earliest studies found large differences however later studies have not supported this evidence. No theoretical hypothesis for any observed differences have been proposed and therefore the relationship between age and joint stiffness is poorly understood.

2.4.5.4 Velocity

It has been shown that human tissues and fluids display non-Newtonian (thixotropic) responses (Fung, 1993) and thus the viscous response changes with increasing velocity. However there is a lack of agreement within the literature about the total joint response to increasing angular velocity. Lamontagne, Malouin, & Richards (1997) found that at slow speeds (< 60°/s) the resistive torque at the ankle (measured at 0° and –10°) joint was very low however this increased significantly at velocities > 60°/s. In a similar study of ankle dorsiflexion, McNair et al (2002) found a significant difference in the resistive torque at speeds as slow as 25°/s. This study is
in agreement with other studies (Huffschmidt & Schwaller, 1987). However these small samples have been mainly undertaken from relatively young volunteers and have explored different ranges of ankle dorsiflexion, different ranges of angular velocity and differing numbers of repetitions. These factors make it difficult to compare findings and to generalise to an elderly population.

A further consideration for velocity is the possibility of reflex activity (Guyton, 1986). However, previous studies have shown little reflex activity in quadriceps and hamstrings at angular velocities of up to 4.189rad/s (240°/s) (Bierman & Ralston, 1965). Studies of the ankle (Lamontagne, Malouin, & Richards, 1997; McNair et al, 2002) have also suggested that the joint may be rotated at velocities approaching those achieved during gait without eliciting significant EMG activity. Hagood et al. (1990) conversely found that reflexive activity of the antagonist muscles during both flexion and extension increased as joint velocity increased. As this study explored muscle activity of antagonists during active movement, it is not clear if this could be generalised to passive movement but does indicate that the there is no clear consensus in the literature on the topic.

2.4.5.5 Environmental Conditions

Wright and Johns (1961) also suggested that changing the temperature also resulted in altered stiffness. Lower temperatures resulted in increased stiffness and vice versa. However this part of the study was only conducted on two subjects. More recent work (Rasker, Peters, & Boon, 1986) in a group of patients with rheumatoid arthritis reported a significant correlation between finger stiffness and outside air humidity but no significant association was found between finger stiffness and temperature (either inside or outside). The value of the correlation coefficients however was not
stated which makes it difficult to determine the strength of the association. The study also suffers from a number of other limitations; it is not stated whether other factors such as finger circumference (which has been shown to significantly influence the results of such studies (Helliwell, Smathers, & Wright, 1994)) were taken into account; no descriptive data is provided and thus no information provided about weather conditions during the three week observation period, therefore making it is difficult to generalise the results and conclusions were based on only a small sample (n = 1) of RA patients who were hospital in-patients at the time of the study. Furthermore, no subjective assessment of stiffness was made. Thus further work is needed to clarify the effect of weather conditions on joint stiffness is required.

2.4.5.6 Joint fluids

Experimentally induced oedema has been shown to increase stiffness in the finger joint (Wright & Johns, 1961). Although little further work has been done in this area, Helliwell (1997) noted that patients who had undergone intra-articular injections of corticosteroids reported increased feeling of stiffness but that in at least one patient, this was not supported by objective evidence. However this study did not specifically look at the effect of oedema on stiffness and provided only anecdotal evidence of stiffness based on one subject.

2.4.5.7 Time of day

The only study that could be found that reported the effect of time of day on stiffness reported that in RA patients, stiffness in the morning was actually lower than that in the afternoon (Rasker, Peters, & Boon, 1986). This was completely unexpected particularly considering that ‘morning stiffness’ is considered as one of the
symptomatic diagnostic indicators of RA. The results however failed to reach significance and the authors hypothesised that this was due to methodological difficulties (as the study was based on hospital inpatients, the study was restricted to data collecting at a particular time of the day).

2.4.5.8 Disuse

Following bedrest, patients frequently report increased levels of stiffness. It is not clear whether this is simply a perceived stiffness or a change in actual stiffness due to decreased muscle strength in relation to passive joint resistance. Woo et al. (1975) found increased resistive torque in rabbit knees following a period of immobilisation. These findings also correlated with the finding that amounts of water and glycosaminoglycans were reduced. This may explain a later study in rats (Brown, Fisher, & Salsich, 1999) which found that 2 weeks of reduced muscle use did not alter muscle stiffness in the hindlimb but noted a reduction in muscle mass. As stiffness had not changed, they concluded that the remaining muscle mass had to be stiffer per gram of tissue and therefore a higher proportion of antagonistic muscle strength was required to overcome the passive resistance to motion. This theory has not been developed further, particularly in humans, however Chesworth & Vandervoort (1995) found that ankles that had been immobilised following fracture had greater passive elastic stiffness than those fractures that had not. This led the authors to suggest immobilisation of muscles may contribute to altered length-tension relationships which in turn influence joint stiffness.
2.4.5.9 Joint position

Riener & Edrich (1999) concluded that a strong relationship existed between passive elastic joint moments and position of adjacent joints. They used curve fitting to develop a model of the passive elastic joint moments although no statistics were offered to support their suggestion that the model represented the experimental data “quite well” nor to support the claim that there was a “strong correlation” between passive elastic moments and joint position. In addition the model presented was based on a “generic subject” without any description of what they meant by this. The findings however do tend to agree with previous work although it is difficult to generalise the findings to a larger population.

2.4.6 Stiffness summary

It is clear from the literature that patients subjectively report stiffness both before and after knee arthroplasty. The aetiology is unclear but is likely to involve a variety of soft tissues. Three methods of quantitative measurement of joint stiffness have been described within the literature (Table 2.4), however those studies that have considered the knee joint have utilised a range of different methods, sample sizes, hip and ankle angles, subject positioning and statistical analysis making it is difficult to compare studies.

Stiffness has been reported in knee affected by OA, rheumatoid arthritis (RA) and patella-femoral pain syndrome as well as ACL-deficient knees. In addition there is some evidence to suggest that stiffness is related to function in some pathological conditions. There have been no studies however of stiffness in the replaced knee and
therefore its contribution to functional limitations in this patient population is unknown.

Table 2.4 Methods to evaluate joint stiffness

<table>
<thead>
<tr>
<th>Method</th>
<th>Advantages</th>
<th>Disadvantages</th>
<th>Previously used to assess</th>
</tr>
</thead>
<tbody>
<tr>
<td>Passive Resistance to Motion Method</td>
<td>Allows measurement of stiffness throughout range</td>
<td>Affected by voluntary or involuntary muscle contractions</td>
<td>MCP joints</td>
</tr>
<tr>
<td></td>
<td>Can be performed at a variety of velocities</td>
<td>Requires fairly complex instrumentation</td>
<td>Healthy knees</td>
</tr>
<tr>
<td></td>
<td>Can determine type of stiffness - elastic, plastic, inertial etc</td>
<td>Joint tested in unweighted position</td>
<td>Following ankle fracture</td>
</tr>
<tr>
<td></td>
<td>Fairly easy to use</td>
<td>Stiffness can be calculated at any point in range</td>
<td></td>
</tr>
<tr>
<td>Pendulum Method</td>
<td>Easy to perform</td>
<td>Affected by voluntary or involuntary muscle contractions</td>
<td>Resistance due to muscle spasticity</td>
</tr>
<tr>
<td></td>
<td>Little instrumentation required</td>
<td>Restricted velocity</td>
<td>Healthy knees</td>
</tr>
<tr>
<td></td>
<td>Quick</td>
<td>Only gives overall values for stiffness</td>
<td>OA knee</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Makes simplified assumptions about the joint complex</td>
<td>Knees with patello-femoral pain</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Joint tested in unweighted position</td>
<td></td>
</tr>
<tr>
<td>Dynamic Stiffness Method</td>
<td>Performed in the weight bearing position</td>
<td>Limb must be weightbearing</td>
<td>Healthy knees</td>
</tr>
<tr>
<td></td>
<td>Not affected by voluntary or involuntary muscle contractions</td>
<td>Requires complex instrumentation</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Test performed at functional velocity</td>
<td>Velocity of movement difficult to standardise</td>
<td></td>
</tr>
</tbody>
</table>
2.5 Literature Review Summary

When the pain and functional limitations of an osteoarthritic knee become too much for the patient to bear, replacement of the affected knee has become the treatment of choice. Whilst the literature shows that the outcome of TKA to be a successful procedure for most patients, however it is also clear that for many, functional limitations persist even at 1 year following surgery. The potential reasons for persistent functional limitations are myriad but stiffness is one possible explanation that has received little attention. There is anecdotal evidence to suggest that patients experience stiffness along with functional limitations but it has never been objectively measured in this group of subjects. Thus this study aims to explore the concept of stiffness following TKA as its subsequent impact on the ability of individuals to go about their activities of daily living.
3 Study aims

This chapter outlines the aims and objectives of the study. As the topic had not been previously studied in detail, the study was intended to be primarily exploratory in nature. Three objectives were proposed.

3.1 Aims and purpose

The overall aim of the study was to pilot a method for the objective quantification of knee joint stiffness following TKA and to undertake a preliminary exploration of the impact of joint stiffness on an individual’s ability to carry out their activities of daily living. The purpose of such a study was to make a contribution to the body of knowledge on factors influencing function following TKA which could be useful to surgeons, therapists and engineers involved in the design of implants, surgery and subsequent rehabilitation of patients undergoing knee arthroplasty.

3.2 Objectives

The study had three objectives. These were to:

1. Develop and evaluate a method for the quantitative assessment of joint stiffness in an elderly orthopaedic population in order to investigate patients’ subjective reports of stiffness through objective measures.

2. Undertake a pilot study to explore the potential impact of knee joint stiffness on the ability of subjects with knee replacement to undertake their activities of daily living.

3. To explore patient’s subjective perceptions of stiffness prior to and following TKA.
4 Biomechanical model of joint stiffness

Joint stiffness was proposed to be just one of the elements that influenced motion of the joint. In order to calculate the stiffness component, a biomechanical model of the motion of the joint during passive flexion and extension was developed.

4.1 Definition of “stiffness”

Stiffness is generally defined as “the amount of force required to produce a given displacement”. As joint motion is rotational, this definition may be considered as the amount of torque required to produce a given angular displacement (Gajdosik, 2001). Using these definitions, joint stiffness may also be described as the passive resistance to motion (PRM) (Heerkens, 1985).

4.2 Development of the mathematic model

The first step in the development of a model which could explain the PRM required identification of all the forces acting on the body system during passive extension and flexion of the knee joint.

As the lower leg passively rotated around the knee, resistance to the angular motion when the muscles are relaxed was provided by a number of moments acting on the body segment (Riener & Edrich, 1999): a dynamic moment resulting from inertia (mass moment of inertia), a moment due to gravity, and a passive moment comprising of elastic and dissipative elements (Esteki & Mansour, 1996).
4.3 Free body diagram

A free body diagram (Figure 4.1) shows the forces acting on shank and foot segment due to inertia and gravity as the leg was passively flexed and extended.

Figure 4.1 Free body diagram of forces acting on the shank and foot during passive flexion/extension.
4.4 Development of the biomechanical model

Motion at the knee joint occurs primarily in the sagittal plane (flexion/extension) and is angular. In order to calculate the torques acting around the knee joint during passive motion, the principle of moments was used in a biomechanical model.

Taking into account the forces acting upon the system identified in the free body diagram (Figure 4.1) the following moment’s equation was developed. Moments were said to act around the centre of rotation of the knee.

\[
T_{PF0} - T_{s&f0} - T_{PR0} - IT_{\theta} = 0
\]

Eq. one

- \( T_{PF0} \) is the torque due to the force applied to the shank and foot to generate passive flexion/extension, at any given angle \( \theta \).
- \( T_{s&f0} \) is the torque due to gravity acting on the mass of the shank and foot, at any given angle \( \theta \).
- \( T_{PR0} \) is the passive resistive torque created by the soft tissues, at any given angle \( \theta \).
- \( IT_{\theta} \) (inertial torque) is the resistance to angular motion created by the mass of the shank and foot, at any given angle \( \theta \).

4.4.1 Torque due to gravity

The torque due to gravity acting on the mass of the shank and foot (Figure 4.1) was calculated using Newtons First Law which states;

\[
F = ma
\]

Eq. two (Hamill & Knutsen, 2009)
and the general equation for calculation of a moment which is;

\[ T = force \cdot r \]  

Eq. three (Hamill & Knutsen, 2009)

where \( r \) represented the perpendicular distance from the line of action of the force to the centre of rotation.

So, torque due to gravity acting on the shank and foot was calculated as;

\[ T_{s f} = mg r_1 \cos \theta \]  

Eq. four

Where, based on Figure 4.1, \( m \) is the mass of the shank and foot, \( g \) is acceleration due to gravity \( r_1 \) is the distance from the centre of rotation to the centre of mass of the shank and foot, and \( \theta \) is the joint angle.

4.4.2 Torque due to inertia

The torque required to overcome the moment of inertia (IT) resulting in angular acceleration can be represented by the angular analog to Newton's Second Law; and is stated by the equation;

\[ T = I \alpha \]  

Eq five (Hamill & Knutsen, 2009)

Where \( I \) is the moment of inertia and \( \alpha \) is the angular acceleration. However this equation only holds true if \( I \) and \( \alpha \) are calculated around the centre of mass of the object (Griffiths, 2006). For systems such as the one described in Figure 4.1 where the object does not spin around an axis which passes through its centre of mass, the object becomes more difficult to spin (compared to one which does spin around its centre of mass) and thus the moment of inertia was recalculated to take this into account. The moment of inertia can be calculated for any axis which lies parallel to
that which acts through the centre of mass as long as the mass of the segment and the perpendicular distance between the parallel axes is known. This concept is known as the Parallel Axis Theorem (Hamill & Knutsen, 2009). In order to calculate the moment of inertia around the centre of rotation of the knee joint in this instance, the moment of inertia was calculated around the proximal joint (the knee). According to Hamill & Knutsen (2009), the moment of inertia around the proximal joint could be taken as:

\[ I_{\text{prox}} = I_{\text{cm}} + mr^2 \]  

Eq. six

Where \( I_{\text{prox}} \) was the moment of inertia around the proximal axis, \( I_{\text{cm}} \) was the moment of inertia around the centre of mass, \( m \) is the mass of the segment and \( r \) is the perpendicular distance between the two axes.

The moment of inertia around the centre of mass was calculated as

\[ I_{\text{cm}} = mk^2 \]  

Eq. seven (Richards, 2008)

Substituting eq. eight into eq. seven gave:

\[ I_{\text{prox}} = mk^2 + mr^2 \]  

Eq. eight

Finally, substituting eq. eight into Eq. five gave;

\[ T = (mk^2 + mr^2)\alpha \]  

Eq. nine

Or simplified this gave

\[ T = m(k^2 + r_1^2)\alpha \]  

Eq. ten
Where \( m \) represents the mass of the shank and foot, \( k \) represents the radius of gyration; \( r_1 \) is the distance from the centre of rotation to the centre of mass (as indicated on Figure 4.1) and \( \alpha \) is the angular acceleration at the centre of rotation.

### 4.4.3 Passive resistance to motion equation

Substituting equations four and ten into equation one gave;

\[
T_{PF} - T_{PR} - mg r_1^2 \cos \theta - m(k^2 + r_1^2)\alpha = 0
\]

Eq. eleven

Thus rearranging the equation to solve for \( T_{PR} \) gave

\[
T_{PR} = T_{PF} - mg r_1^2 \cos \theta - m(k^2 + r_1^2)\alpha
\]

Eq. eleven

### 4.5 Assumptions

The following assumptions were made:

1. The shank and foot has a fixed mass, which could be considered as acting at the centre of mass. This mass could be approximated from previous equations described within the literature.

2. The location of the centre of mass of the shank and foot remained fixed during the movement. Again the location of the centre of mass was estimated using previously published anthropometrical data.

3. The knee joint was considered to be a hinge type joint acting only in the sagittal plane.

4. The mass moment of inertia of the shank and foot remained constant throughout the movement.
5. The length of the shank and foot remained constant throughout the movement.


7. The transepicondylar axis was considered as approximating the axis of rotation in flexion/extension of the knee joint.

8. The instantaneous centre of rotation of the knee joint remained constant throughout the movement.

9. The passive force PF (indicated on the free body diagram, figure 4.1) would have no effect on the mass of the thigh.

4.6 Estimation of anthropometrical data

Anthropometrical data was calculated using equations previously reported in the literature. Table 4.1 outlines the parameters and the equations used.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Equation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length of shank and foot</td>
<td>0.285 x height</td>
</tr>
<tr>
<td>Mass of shank and foot</td>
<td>0.058 x total body mass</td>
</tr>
<tr>
<td>Radius of centre of mass of shank and foot</td>
<td>0.475 x length of segment</td>
</tr>
<tr>
<td>Radius of gyration of shank and foot</td>
<td>0.735 x length of segment</td>
</tr>
</tbody>
</table>

* (Drillis, Contini, & Bluestein, 1966)
† (Clauser, McConville, & Young, 1969)
‡ (Plagenhoef, 1966)
4.7 Calculation of angular displacement, velocity and acceleration

The second derivative of the displacement-time function was used to calculate angular acceleration \( \alpha \)

\[
\alpha = \frac{d^2 \theta}{dt^2}
\]

4.8 Calculation of stiffness parameters

The torque contributed by the passive resistance to motion, along with angular displacement could then be used to determine the stiffness parameters of the knee joint.

Previous work has shown that stiffness is not linear and varies through range (McFaul & Lamontagne, 1998). During mid-range, values were very low, whilst in flexion and extension, they were much higher. Thus stiffness was calculated in flexion, extension and midrange. Furthermore it has been shown that plots of passive elastic stiffness against joint angle demonstrate hysteresis and therefore the direction of motion is also important (Mansour & Audu, 1986). As part of the rationale for this study was to determine why TKA patients fail to utilise available range of motion, it was decided to look at flexion stiffness as the knee flexed and extension stiffness as the knee extended.

4.8.1 Passive elastic stiffness

Passive resistance to motion was plotted against knee angle. Stiffness was defined as the slope of the line relating these two characteristics. Flexion stiffness was defined as the slope of the line beginning at the point during knee flexion at which stiffness was seen to significantly increase. Extension stiffness was defined as the slope of the
line beginning at the point during knee extension where stiffness was seen to significantly increase.

4.8.2 Other stiffness related variables

The point in range of motion at which stiffness was seen to increase significantly was identified as the stiffness threshold angle and was also recorded. Finally, the resistive torque value at which stiffness was seen to significantly increase, labelled as stiffness threshold torque, was also recorded.
5 Instrumentation development

Chapter 4 described the biomechanical model of the forces acting on the knee joint and developed an equation which would allow the passive resistance to motion provided by the soft tissues to be estimated. This chapter outlines the development of the instrumentation which was used to measure the total resistance to passive motion (T_{TR}) and to subsequently calculate stiffness.

5.1 System requirements

In order to measure the total resistance to passive motion, it was determined that the system would require a method of passively flexing and extending the lower limb, a device capable of measuring the torque required to rotate the lower limb around the knee, a device capable of measuring the angular displacement of the knee and a method by which all data could be captured simultaneously and transferred to a PC for processing.

A method by which it could be ensured that the motion was truly passive was also required.

The system had several requirements which were taken into account during the planning and development. It had to be:

- portable in order that it might be easily moved between testing sites
- affordable
- able to be operated by a single operator

There were no commercially available systems that could measure the parameters identified and fulfil the requirements outlined above. Certain isokinetic
dynamometers such as those offered by Biodex\textsuperscript{6} have a passive mode which moves the limb at a predetermined velocity through a determined range of motion. Several studies, albeit not in this area, have utilised such a system (Blackburn et al, 2004b; Gajdosik, Van Der Linden, & Williams, 1999; Hagood et al, 1990) however they are not portable and are expensive which prohibited their use in this particular study.

5.2 System Components

This section describes the individual components that made up the testing rig and also provides a justification for the overall design of the testing rig.

5.2.1 Passive movement of the lower limb

Previous studies which have measured the passive resistance to motion at the knee, have utilised a side lying position (Mansour & Audu, 1986). The advantage of side lying was that flexion/extension of the lower limb is not subject to gravitational forces, thus simplifying the calculations. However, co-morbidities, often present in those who undergo total knee arthroplasty (Lingard et al, 2004), may have limited the ability of the participants to tolerate lying positions. Thus it was preferable to place subjects in an upright seated position, with their back and thigh supported. A rig was designed consisting of an axis with an arm on each side. A height adjustable footplate on one arm allowed the participants foot to be attached to the rig arm. A handle on the other arm allowed an operator to flex and extend the subjects knee passively. In order to take into account gravitational forces anthropometric data were also necessary.

\textsuperscript{6} Biodex Medical Systems, New York, USA
As has been previously noted, biological tissues demonstrate viscoelastic properties. The stiffness calculations were therefore modelled to be proportional to the velocity of the angular displacement. In order to ensure that any differences in the results could not be attributed to differences in the velocity of the passive motion, a pilot study was necessary to establish the reliability of the researcher to move the leg of the subject at a consistent velocity.

5.2.2 Measurement of torque

A force transducer incorporated into the rig provided a method by which the resistance to motion offered by the lower limb during passive flexion/extension could be measured.

A transducer has been defined as “a device that receives a physical stimulus and changes it into another measurable physical quantity through a known relationship” (National Physical Laboratory & Institute for Measurement and Control, 1998).

There were many different types of transducer available for the measurement of force and the National Physical Laboratory (National Physical Laboratory & Institute for Measurement and Control, 1998) provided guidelines for choosing an appropriate type of measurement device. They stated that the following factors should be taken into consideration:

1. The range of force to be measured
2. The number of loading points
3. The direction of the forces
4. The duration and rate of loading.
When deciding on the type of transducer most suitable for incorporation into the rig, these four points were taken into account.

In considering the range of force to be measured, the maximum estimated torque due to the mass of the shank and foot was calculated. Previous work by the author, on a knee arthroplasty population in the Lothian area (Lane, Lingard, & Howie, 2004) revealed a 95% confidence interval of 75.03 – 80.76 kg for weight and 1.63 – 1.67m for height. Using the upper bound of the 95% confidence interval as a maximum value and the anthropometric data outlined in chapter 4, the maximum potential torque due to the mass of the shank and foot was calculated (Table 5.1).

Table 5.1  Anthropometric characteristics of proposed study population

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Equation</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper 95% limit of height</td>
<td></td>
<td>1.67m</td>
</tr>
<tr>
<td>Upper 95% limit of weight</td>
<td></td>
<td>80.76kg</td>
</tr>
<tr>
<td>Length of shank and foot</td>
<td>0.285 x height</td>
<td>0.476m</td>
</tr>
<tr>
<td>Mass of shank and foot</td>
<td>0.058 x total body mass</td>
<td>4.68kg</td>
</tr>
<tr>
<td>Weight of shank and foot</td>
<td>Mass of shank and foot x 9.81</td>
<td>45.910</td>
</tr>
<tr>
<td>Radius of centre of mass of shank and foot</td>
<td>0.475 x length of segment</td>
<td>0.226m</td>
</tr>
<tr>
<td>Maximum torque created by weight of shank and foot</td>
<td>Weight of shank and foot x radius of centre of mass</td>
<td>10.376Nm</td>
</tr>
</tbody>
</table>

Previous work by McFaull & Lamontagne (1998) reported passive elastic moments at the knee joint albeit in a healthy younger population. Although summary statistics were not provided, data from a ‘typical trial’ was presented which showed maximum values of around 25Nm. Thus it was estimated that maximum resistance to motion

* (Drillis, Contini, & Bluestein, 1966)

✝ (Clauser, McConville, & Young, 1969)
values would be around the order of 35Nm. Thus it as determined that if the angular velocity were kept as close to a constant as possible, a transducer which could measure up to 100Nm in either direction would allow for a large margin of error.

Several different points of loading were possible on the rig designed to move the lower limb passively. The main loading points in the system were deemed to be; 1) the lever arms of the rig, 2) the axis of rotation itself.

The first type of force transducer to be considered for the current study was a strain gauge load cell which could be incorporated into the lever arm of the rig. The cell would measure the force tending to bend the lever arm and thus the resistive torque could be calculated. The load cell however was heavy and incorporated into the lever arm, would increase the inertia of the rig.

A search of services on the internet revealed a torque transducer\textsuperscript{7} which was capable of measuring the rotary torque applied to the shaft of the transducer. This approach seemed ideal as the transducer could form the axis around which the rig could rotate and thus would have no direct influence on the magnitude of the measured values. The transducer uses surface acoustic wave devices which measure the change in resonant frequency caused when a rotary torque is applied to the shaft (Figure 5.1).

\textsuperscript{7} E300/RWT Rayleigh Wave Rotary Torque Transducer, Sensor Technology Ltd, Banbury, Oxon
A range of specifications was available which allowed a transducer to be chosen which would match the requirements of the measurement system.

The torque transducer was capable of measuring static or dynamic torque. Clockwise torques produced a positive polarity output whilst anti-clockwise torques produced a negative output. The transducer output was then connected to a transducer display interface\(^8\) via a dedicated cable. The transducer was factory calibrated with equipment that conformed to National Physical Laboratory Standards. The specifications of the transducer are detailed in Table 5.2.

---

\(^8\) E302 Advanced Rayleigh Wave Torque Transducer Display Interface Module, Sensor Technologies, Banbury, Oxon
Table 5.2 Technical specification of the torque transducer

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Min FSD*</td>
<td>0-20Nm</td>
</tr>
<tr>
<td>Max FSD</td>
<td>0-100Nm</td>
</tr>
<tr>
<td>Cable length</td>
<td>2m</td>
</tr>
<tr>
<td>Outputs</td>
<td>From E302 module (± 5V)</td>
</tr>
<tr>
<td>Power Supply</td>
<td>From E302 module</td>
</tr>
<tr>
<td>Accuracy</td>
<td>± 0.25% FSD</td>
</tr>
<tr>
<td>Bandwidth</td>
<td>Better than 2KHz</td>
</tr>
<tr>
<td>Output frequency change</td>
<td>± 200KHz for full scale at 500 microstrain</td>
</tr>
<tr>
<td>Temperature range</td>
<td>-10°C to + 50°C</td>
</tr>
<tr>
<td>Interface readout</td>
<td>E302</td>
</tr>
<tr>
<td>Safe mechanical overload</td>
<td>300% of rating</td>
</tr>
<tr>
<td>Memory</td>
<td>Embedded non-volatile memory chip</td>
</tr>
<tr>
<td>Hysteresis</td>
<td>Better than 0.1%</td>
</tr>
<tr>
<td>Bearings</td>
<td>Deep grooved shielded bearings with oil lubrication</td>
</tr>
<tr>
<td>Temperature co-efficient</td>
<td>Less than 0.01% per °C</td>
</tr>
</tbody>
</table>

* FSD = full scale deflection

The direction of the forces was rotary and dynamic in nature, changing as the leg moved through range. Thus a torque transducer, designed to measure rotational forces was ideal. The system provided an interface which updated the data at a rate of 100Hz and could measure continuously for as long as was necessary.

Although it was advantageous for the transducer to be incorporated into the axis of rotation (and thereby had no influence on the magnitude of the forces measured), this introduced a different complication. Studies of isokinetic dynamometry have shown that misalignment between the axis of rotation of the dynamometer and the knee joint axis of rotation can influence the torque measured (Croisier, Ciavatta, & Forthomme, 2005; Keating & Matyas, 1996). In the normal knee, the so-called “screwhome” mechanism (translation combined with rotation) results in an unequal translation of
the medial and lateral femoral condyles (Freeman & Pinskerova, 2005). Despite this, the transepicondylar axis, defined as a line which joins the most prominent points on the two femoral condyles, has been shown to be a good approximation of the optimal flexion axis (Churchill et al, 1998; Most et al, 2004) and is regarded as the standard for the measurement of knee flexion - extension (Wu & Cavanagh, 1995). Alignment however of the axis of rotation of the testing rig with the lateral epicondyle may have subject to error. In a review of influences on dynamometry measures, Keating & Matyas (1996) suggested that alignment whilst the knee was in 90° of flexion may lead to misalignment in full extension of several centimetres however no references were offered in support of this claim. Croisier, Ciavatta, & Forthomme (2005) reported that moving the knee axis up to 6cm in front of the dynamometer had no influence on torque, although moving 6cm behind did have a significant influence. This study however failed to describe the method by which alignment had been established and therefore the conclusions must be considered with some scepticism. One method by which alignment can be determined is using an optoelectronic motion analysis system such as Vicon. Such systems track the trajectory of a skin-mounted retroreflective marker. Soft tissue artefacts (STA) as the skin moves over bony landmarks can limit the sensitivity of the measurements although a recent study found the intersubject variability to be low (Gao & Zheng, 2008) and the method remained preferable to the invasive alternatives such as bone pins. Thus it was important that the axis of the knee joint and the axis of rotation of the torque transducer were optimally aligned.

---

9 VICON,Oxford.
5.2.3 Measurement of angular displacement

The method of measuring angular displacement had to be able to measure continuously throughout motion and synchronously with the torque transducer. Although an optoelectronic system such as Vicon would have fulfilled these requirements, such systems are generally laboratory based and would be difficult to transport to a variety of clinical testing sites. It was also possible to measure angular rotation using an optical rotary speed sensor on the torque transducer. Although this may have provided reliable data, the data would have related to the motion of the lever arms of the testing rig rather than the tibia with respect to the femur. An electrogoniometer\textsuperscript{10} attached across the knee joint was therefore chosen to measure the knee joint angular displacement in the sagittal plane. Electrogoniometers have previously been shown to be valid and reliable in the measurement of joint motion (Rowe et al., 2001).

5.2.4 Passivity of muscles

Passive muscles are relatively electrically inactive and therefore it was decided to use electromyography (EMG) to monitor the activity of the quadriceps muscles during passive motion. It was assumed that a lack of electrical activity in quadriceps during knee flexion and extension would be sufficient to indicate that the movement was entirely passive. There is little reported work on the level of electrical activity of passive muscles however other studies that have used EMG to ensure muscles were passive have used a variety of methods to analyse the data. McNair et al (2002) used a limit of 1% of maximal voluntary contraction (MVC) whilst others (McFaull &

\textsuperscript{10} Biometrics Ltd, Gwent
Lamontagne, 1998; McHugh et al., 1992) simply identified onset of activity by looking for sudden changes in voltage. As MVC are difficult to elicit particularly in those with knee pain, it was decided to identify the onset of activity by a significant increase in quadriceps muscle activity.

5.2.5 System Assembly

The arm and handle of the testing rig were machined from aluminium which was lightweight but strong. A height adjustable foot-plate was attached to the arm. The arm and handle were cold welded to the shaft of the transducer thus application of force to the handle turned the shaft of the transducer and this torque was transferred to the arm of the system. By aligning the shaft of the transducer with the axis of rotation of the knee joint and attaching the ankle of the subject to the cross piece, the handle could be turned to elicit flexion and extension at the knee joint.

The testing rig and torque transducer were mounted on a solid base. The system was portable and could be moved to ensure alignment with any plinth on which the subject was seated. This enabled the system to be used wherever a plinth was available.

5.2.6 Data Acquisition System

The torque transducer and electrogoniometer produced an analogue signal (Volts), which subsequently required to be converted to a digital signal before being processed. The torque transducer and electrogoniometer were each connected to a data acquisition board\textsuperscript{11} which in turn was connected to the USB 2.0 port of a

\textsuperscript{11} DT9801 Function Module, Data Translation Inc., Marlboro, MA
portable computer\textsuperscript{12}. LabVIEW 7.0 Express\textsuperscript{13} was used to control data acquisition and to store data. DT-LV Link software\textsuperscript{14} provided pre-written Virtual Instrument’s (VI’s) which could be used to program the data acquisition (DAQ) board within LabView. Figure 5.2 shows how the components of the system linked to each other.

\begin{itemize}
  \item \textsuperscript{12} Toshiba
  \item \textsuperscript{13} National Instruments Corp, Austin, Texas
  \item \textsuperscript{14} Data Translation Inc. Marlboro, MA
\end{itemize}
Although the torque transducer was factory calibrated and the interface provided a read-out in Nm, the signal that was recorded from the interface unit by the data
acquisition board was in Volts. A pilot study was therefore required to establish the
calibration coefficients necessary in order to convert the voltage to Nm. Likewise,
the output from the EG was recorded in Volts and a pilot study was required in order
to determine the calibration coefficients necessary to convert the voltage into
degrees. The pilot studies also determined the reliability of both measurement
systems.

5.2.6.1 Sampling Frequency

Previous work has reported a wide range of sampling frequencies ranging from 25Hz
to 1000Hz (McFaull & Lamontagne, 1993; Myles et al, 2001; Nordez, Cornu, &
McNair, 2006; Owen et al., 2005; Riener & Edrich, 1999) for the collection of torque
and displacement data during similar activities. No study provided a rationale for
their choice of sampling frequency however the Nyquist-Shannon sampling theorem
states that the signal must be sampled at a frequency that is at least twice as high as
the highest frequency in the signal itself (Winter & Patla, 1997). Thus according to
this theory, if the knee is rotated at 5⁰/second, then a sampling frequency of 10Hz
should be sufficient to capture displacement data with a detail of individual degrees.
It was recommended however that in practice, the sampling frequency is 4 times the
highest frequency in the signal (Stergiou, 2004). Stergiou (2004) however cautioned
that setting too high a sampling frequency can create practical problems in data
processing as signal may demonstrate no change for many frames. Too low a
sampling frequency will result in missed data. Therefore it is important to choose an
efficient sampling frequency that adequately covers the motion under investigation.
As there was little work on which to base the decision with regards to sampling
frequency, a pilot study was required.
5.3 System Assumptions

Following the development of the system, a further three assumptions were added to the 9 outlined in chapter 4. It was assumed that:

10. The axis of rotation of the knee joint and the centre of rotation of the torque transducer remained aligned throughout the movement.

11. The position of the centre of mass of the equipment remained constant throughout testing.

12. The mass of the thigh was entirely supported by the plinth on which the participant was seated.

The calculations outlined in chapter 4 were based on the assumptions outlined in section 4.5 and above. It was recognised however that in some cases, the plinth may have not provided adequate support to the thigh and therefore the corrections made within the calculations for gravity acting on the mass of the shank and foot might have been inaccurate. In these cases, the footplate of the rig would have contributed to the overall support of the thigh and shank & foot and thus contributed to the overall torque measured by the rig.

5.4 Output and data processing

The .txt file containing raw torque and electrogoniometer data was then processed using a separate LabView programme. This program read the file and converted raw data into N.m (torque) and radians (displacement). Biomechanical data however is often ‘noisy’ and subsequent calculations such as velocities and accelerations can compound the measurement errors. Therefore it was necessary to use a method by which errors were smoothed or filtered out. Data was also filtered using a low-pass
4th order Butterworth filter with a cutoff ($f_c$) of 2Hz. Angular displacement data was derived in order to obtain angular velocity (1\textsuperscript{st} derivative) and acceleration (2\textsuperscript{nd} derivative) data. The data was then written to another .txt file for processing in Excel.

Total torque, acceleration and anthropometric data was used to calculate the passive resistance to motion offered at the knee. Elastic stiffness was calculated from passive resistance to motion (torque) and angular displacement (degrees) data. At the point where the passive elastic stiffness could be seen to increase significantly, threshold elastic stiffness angle and threshold elastic stiffness torque values were also recorded (Wood et al, 2005). Calculation of the passive elastic stiffness, threshold elastic stiffness angles and torque variables was undertaken using a MatLab routine. This process is outlined in Figure 5.3.
As the system had not been previously described for the measurement of stiffness, a pilot study was required in order to determine the reliability of the stiffness measures.
5.5 Pilot Studies

Before the system was tested on a clinical population, pilot studies were undertaken within the human performance laboratory (HPL) and the motion analysis laboratory (MAL) at QMU. These are outlined in Table 5.3.

Table 5.3 Pilot studies and their aims

<table>
<thead>
<tr>
<th>Pilot</th>
<th>Aims</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Establish scaling data for the electrogoniometer and establish reliability</td>
</tr>
<tr>
<td>2</td>
<td>Confirm validity of the scaling data provided for the torque transducer</td>
</tr>
<tr>
<td>3</td>
<td>Explore alignment of the knee and centre of rotation of the measurement rig</td>
</tr>
<tr>
<td>4</td>
<td>Establish validity of the system to measure stiffness</td>
</tr>
<tr>
<td>5</td>
<td>Determine reliability of the velocity of passive motion</td>
</tr>
<tr>
<td>6</td>
<td>Identify the optimal sampling frequency and filtering parameters</td>
</tr>
<tr>
<td>7</td>
<td>Intra and inter day reliability of stiffness data</td>
</tr>
</tbody>
</table>

5.5.1 Ethical Considerations

As this pilot work was undertaken at Queen Margaret University on healthy, normal subjects, approval to carry out pilot studies in the HPL was sought and granted from Queen Margaret University Physiotherapy Subject Area Ethics Panel.

5.5.2 Data Processing

All data was acquired, scaled and filtered using Labview 7.0 Express (as described in section 5.2.6) and processed with Excel. Statistical analyses were undertaken using SPSS Version 16.0.
5.5.3 Electrogoniometer scaling

5.5.3.1 Methods

In order to determine scaling coefficients, the output from the electrogoniometer (in volts) was measured at a series of predetermined angles. The electrogoniometer was attached to a universal goniometer. Values were recorded in 10° increments from 0° - 140° – 0°. Each angle was held for 5 seconds. In order to determine inter-session reliability, the procedure was repeated a week later.

Inter-session reliability was evaluated using Bland and Altman plots (Bland JM & Altman DG, 1986) to identify any systematic change and intra-class correlation coefficients (model 3,1) to determine agreement (Shrout & Fleiss IN (Denegar & Ball, 1993). Although some authors have cautioned against the use of labels to interpret ICC’s (Lexell & Downham, 2005) they may be helpful if the limitations of the ICC’s are considered. Fleiss (1986) suggested that ICC values of > 0.75 represented “excellent” reliability and that values between 0.4 and 0.75 were considered as “fair to good reliability”. Lexell & Downham (2005) suggested that several methods are used together to interpret reliability and therefore the standard error of measurement (Hopkins, 2000) was also calculated in order to determine the typical error that can be expected in the measurement of the voltage. Once the reliability was established, scaling coefficients were calculated using linear regression analysis.

5.5.3.2 Results

Firstly the reliability of the electrogoniometer output between testing sessions was determined. A Bland and Altman plot was constructed (Figure 5.4) to assess the level
of agreement between the values obtained over the two testing sessions. The solid black line at 0.119v indicates the mean bias and the two dotted lines indicate the upper and lower 95% limits of agreement.

Figure 5.4 Bland and Altman plot (mean volts vs difference in volts) for days 1 & 2.

The mean bias in the readings was 0.119 (95% CI -0.061 – 0.229) volts suggesting that the readings from day 2 were, on average, slightly lower than those from day 1. The relationship between the bias and the mean was determined by correlation (Pearsons Product Moment Correlation Coefficient). The r value was 0.495 (p = 0.006) which according to Munro BH (2001) was moderate. This suggested that the bias increased as the voltage increased, raising the possibility of a systematic bias. The r value dropped to 0.28, a very weak relationship, if the two values which lie outside the limits of agreement were not included in the correlation. However, as the
graph clearly demonstrates, the magnitude of the bias was very small compared to
the actual mean voltage values.

An ICC (3,1) calculated to determine the agreement of the raw data between day 1
and day 2 was 0.990 (95% CI 0.815 – 0.997). The SEM of the volts was 0.0582
volts. Together these statistics supported the evidence that the difference in voltage
measurement between the two days was very small.

The reliability analysis suggested that there was generally good agreement between
the days. An average of the two days was taken and a linear regression equation was
then constructed in order to predict the actual degrees from the electrogoniometer
output (Figure 5.5). The residuals were analysed to determine the accuracy of the
prediction equation.

Figure 5.5 The relationship between the universal goniometer and the
electrogoniometer output.
The relationship between the two variables was strong ( \( r = 0.999, r^2 = 0.997 \)). The regression equation was determined as

\[
\text{Degrees} = 40.112 \text{volts} + 4.254. \tag{5.1}
\]

The standard error of the residuals was 2.168°. Using the scaling equation (Equation 5.1), the data from day 1 and day 2 was converted into degrees and reanalysed for reliability in order to get a further idea of the day to day error of the electrogoniometer in degrees.

The mean bias for the data in degrees was 4.776° (95% CI -2.464 – 12.016) (Figure 5.6). As data had been scaled similarly, the reliability coefficients are the same as for the voltage data. The SEM was recalculated as 2.301°.

Figure 5.6 Reliability of electrogoniometer using data in degrees.
5.5.3.3 Conclusion

The inter-session reliability of the electrogoniometer was established as being good with minimal error in measurement. The linear regression equation demonstrated a good fit and therefore the scaling coefficients provided by the model could be applied to the raw voltage data.

5.5.4 Torque transducer reliability and scaling pilot

The manufacturers of the torque transducer provided a scaling factor of 20 for converting the voltage output from the torque transducer into Nm. The aim of this second pilot study was to determine the reliability of the raw output (volts) and to verify this scaling factor.

5.5.4.1 Methods

Data was taken with the system unweighted and weighted with a series of weights from 7 N to 47 N. It was predicted in section 5.2.2. that the maximum weight of the patients shank and foot would be around 46 N and therefore the weights applied to the system represent an appropriate maximum torque. The system was moved from 0° – 90° – 0° in 10° increments. At each increment the movement was paused to allow a couple of seconds of torque data to be collected. The mean output value for this couple of seconds data was recorded for each angle (Appendix 1). Three trials were recorded for each condition.

The reliability of the raw output was determined using ICC’s and the scaling factor verified using linear regression analysis.
5.5.4.2 Results

The first step was to establish the reliability of the torque transducer output. As two values for each angle were recorded (as the rig arm was moved from 0 – 90° and as it was moved from 90 – 0°), intra-trial reliability was first established. Poor intra-trial reliability could have indicated hysteresis in the system. Table 5.4 demonstrates the intra-trial ICC (model 3,1) values for each trial for each weighted condition. Each ICC represents the agreement between the torque output (volts) as the rig moves from 0°-90° and 90°-0°. Raw data is included in Appendix 1.

Table 5.4 Intra-trial reliability of unscaled torque transducer data

<table>
<thead>
<tr>
<th>Applied weight</th>
<th>Intra-trial 1 (95% CI)</th>
<th>Intra-trial 2 (95% CI)</th>
<th>Intra-trial 3 (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>unweighted</td>
<td>0.990 (0.960 -0.998)</td>
<td>0.998 (0.990 – 1.000)</td>
<td>0.981 (0.913 – 0.996)</td>
</tr>
<tr>
<td>4.983N</td>
<td>0.994 (0.970 – 0.999)</td>
<td>0.988 (0.853 – 0.998)</td>
<td>0.960 (0.817 – 0.992)</td>
</tr>
<tr>
<td>10.006N</td>
<td>0.998 (0.993 – 1.000)</td>
<td>0.998 (0.928 – 1.000)</td>
<td>0.991 (0.906 – 0.998)</td>
</tr>
<tr>
<td>14.381N</td>
<td>0.991 (0.954 – 0.998)</td>
<td>0.992 (0.968 – 0.998)</td>
<td>0.998 (0.990 – 0.999)</td>
</tr>
<tr>
<td>19.404N</td>
<td>0.995 (0.976 – 0.999)</td>
<td>0.998 (0.978 – 1.000)</td>
<td>0.990 (0.221 – 0.999)</td>
</tr>
<tr>
<td>23.917N</td>
<td>0.997 (0.647 – 1.000)</td>
<td>0.999 (0.997 – 1.000)</td>
<td>0.998 (0.991 – 1.000)</td>
</tr>
<tr>
<td>28.939N</td>
<td>0.998 (0.993 – 1.000)</td>
<td>0.998 (0.990 – 0.999)</td>
<td>0.994 (0.973 – 0.999)</td>
</tr>
<tr>
<td>34.237N</td>
<td>0.999 (0.994 – 1.000)</td>
<td>0.992 (0.966 – 0.998)</td>
<td>N/A</td>
</tr>
<tr>
<td>39.260N</td>
<td>0.999 (0.996 – 1.000)</td>
<td>0.999 (0.994 – 1.000)</td>
<td>0.995 (0.976 – 0.999)</td>
</tr>
<tr>
<td>44.734N</td>
<td>0.997 (0.987 – 0.999)</td>
<td>0.992 (0.966 – 0.998)</td>
<td>0.999 (0.997 – 1.000)</td>
</tr>
</tbody>
</table>

As excellent intra-trial reliability was established (all ICC values were > 0.9), an average value for each angle was calculated and used to determine the inter-trial reliability (Table 5.5).
Table 5.5 Inter-trial reliability of the unscaled torque transducer data

<table>
<thead>
<tr>
<th>Applied weight</th>
<th>ICC (3,1)</th>
<th>CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>unweighted</td>
<td>0.981</td>
<td>0.899 – 0.994</td>
</tr>
<tr>
<td>7.122N</td>
<td>0.987</td>
<td>0.972 – 0.995</td>
</tr>
<tr>
<td>12.145N</td>
<td>0.996</td>
<td>0.992 – 0.999</td>
</tr>
<tr>
<td>16.520N</td>
<td>0.995</td>
<td>0.990 – 0.998</td>
</tr>
<tr>
<td>21.543N</td>
<td>0.995</td>
<td>0.989 – 0.998</td>
</tr>
<tr>
<td>26.055N</td>
<td>0.998</td>
<td>0.994 – 0.999</td>
</tr>
<tr>
<td>31.078N</td>
<td>0.998</td>
<td>0.995 – 0.999</td>
</tr>
<tr>
<td>36.375N</td>
<td>0.995</td>
<td>0.986 – 0.998</td>
</tr>
<tr>
<td>41.398N</td>
<td>0.999</td>
<td>0.997 – 0.999</td>
</tr>
<tr>
<td>46.872N</td>
<td>0.996</td>
<td>0.991 – 0.998</td>
</tr>
</tbody>
</table>

As excellent inter-trial reliability was also established (all ICC values > 0.9), a mean of the three trials was used to calculate scaling co-efficients.

As the mass and the position of the centre of mass of the rig arms were unknown an equation was developed to estimate the output from the torque transducer that was due to the mass of the rig alone. The torque due to weight of the rig was a product of the angular displacement, the plot of torque against angular displacement should have produced a sine-curve. Therefore curve-fitting was used to predict torque from displacement (Figure 5.7). Regression analysis with SPSS (v12.0) produced a second-order polynomial equation with an r² value of 0.996.

\[
\text{Volts} = 1.3E-0.5x^2 + 0.0026x + 0.0383
\]

Equation 5.2
Where $x =$ displacement in degrees

Figure 5.7 Unweighted torque transducer output against angle

The predicted torque due to the weights was then calculated. Figure 5.8 shows the free body diagram used to estimate the torque due to the applied weights.

Figure 5.8 Free body diagram of the torque transducer arm with applied weight
The torque due to the weights ($T_w$) was calculated using the following equation

$$T_w = r \times (\sin \theta \times W)$$

Equation 5.3

The output from the torque transducer was calculated as the torque due to the mass of the rig plus the torque due to the weights applied.

$$\text{Total torque} = \text{torque due to rig mass} + \text{torque due to weights}$$

Equation 5.4

By using the polynomial (Equation 5.2) to calculate the output due only to the mass of the rig, the output from the transducer due to the weights could be determined. The predicted torque due to the weights was known (Equation 5.3) and therefore linear regression techniques could be used to determine the scaling factors used to convert the output into torque. Plots of torque transducer output in volts against the predicted torque at that angle are shown in Appendix 1.

The predicted torque (calculated from Equation 5.3) and the raw torque transducer output was subjected to linear regression analysis. This produced a prediction equation for each condition which would predict torque from the raw volts. Table 5.6 outlines the equations and the $r^2$ value.
Table 5.6 Regression equations for torque from raw voltage

<table>
<thead>
<tr>
<th>Condition</th>
<th>( r^2 )</th>
<th>Regression equation</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.983N</td>
<td>0.986</td>
<td>( y = 19.970x - 0.1032 )</td>
</tr>
<tr>
<td>10.006N</td>
<td>0.9933</td>
<td>( y = 19.843x - 0.2008 )</td>
</tr>
<tr>
<td>14.381N</td>
<td>0.9951</td>
<td>( y = 19.885x - 0.0152 )</td>
</tr>
<tr>
<td>19.404N</td>
<td>0.9967</td>
<td>( y = 19.890x + 0.0818 )</td>
</tr>
<tr>
<td>23.917N</td>
<td>0.9971</td>
<td>( y = 20.194x + 0.1276 )</td>
</tr>
<tr>
<td>28.939</td>
<td>0.9973</td>
<td>( y = 20.121x + 0.0456 )</td>
</tr>
<tr>
<td>34.237N</td>
<td>0.9988</td>
<td>( y = 18.837x + 0.1531 )</td>
</tr>
<tr>
<td>39.260N</td>
<td>0.9982</td>
<td>( y = 20.489x + 0.3981 )</td>
</tr>
<tr>
<td>44.734N</td>
<td>0.9968</td>
<td>( y = 19.988x - 0.1807 )</td>
</tr>
</tbody>
</table>

Where \( y = \) torque and \( x = \) volts

It can be seen that the conversion factors estimated by the regression analysis range from 18.837 – 20.489 and therefore closely match the scaling factor of 20 provided by the manufacturer of the torque transducer. Therefore it was decided to explore the validity of this scaling factor by using it to calculate torque from the raw data and determining the level of agreement with the predicted torque using Bland and Altman’s Limits of Agreement (Bland & Altman, 1986).

Table 5.7 shows the bias (scaled data – applied torque) under each condition, along with the upper (ULA) and lower (LLA) limits of agreement as described by Bland and Altman. Min and max values for the actual torque values were calculated to place the magnitude of the bias into context. A minus value in the min/max boxes simply represents the direction in which the torque transducer was being rotated.
Table 5.7 Bland and Altman Limits of Agreement for scaled data and applied torque

<table>
<thead>
<tr>
<th>Condition (Nm)</th>
<th>Bias (Nm)</th>
<th>ULA (Nm)</th>
<th>LLA (Nm)</th>
<th>Min (Nm)</th>
<th>max (Nm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.983N</td>
<td>0.101</td>
<td>0.298</td>
<td>-0.096</td>
<td>-2.462</td>
<td>0.040</td>
</tr>
<tr>
<td>10.006N</td>
<td>0.179</td>
<td>0.453</td>
<td>-0.096</td>
<td>-4.963</td>
<td>0.047</td>
</tr>
<tr>
<td>14.381N</td>
<td>-0.009</td>
<td>0.327</td>
<td>-0.347</td>
<td>-7.254</td>
<td>0.100</td>
</tr>
<tr>
<td>19.404N</td>
<td>-0.114</td>
<td>0.259</td>
<td>-0.488</td>
<td>-9.825</td>
<td>0.18</td>
</tr>
<tr>
<td>23.917N</td>
<td>-0.057</td>
<td>0.378</td>
<td>-0.493</td>
<td>-12.027</td>
<td>-0.173</td>
</tr>
<tr>
<td>28.939N</td>
<td>0.007</td>
<td>0.512</td>
<td>-0.499</td>
<td>-14.511</td>
<td>-0.210</td>
</tr>
<tr>
<td>34.237N</td>
<td>-0.794</td>
<td>0.013</td>
<td>-1.601</td>
<td>-17.816</td>
<td>-0.207</td>
</tr>
<tr>
<td>39.260N</td>
<td>-0.108</td>
<td>0.527</td>
<td>-0.744</td>
<td>-19.719</td>
<td>-0.240</td>
</tr>
<tr>
<td>44.734N</td>
<td>0.173</td>
<td>1.015</td>
<td>-0.669</td>
<td>-22.416</td>
<td>-0.233</td>
</tr>
</tbody>
</table>

Plots of the bias against the applied torque are available in appendix 1.

It was expected that no correlation would be seen between the bias and the mean values (Bland & Altman, 1986). Although the Bland and Altman plots could be perceived to indicate some kind of systematic bias (distinct patterns can be seen in the plots), when the magnitude of the differences against the means was considered, the bias was generally low and the differences were within that which might be expected due to natural variance (the 95% confidence limits).

5.5.4.3 Conclusion

The torque transducer showed excellent intra and inter-trial reliability. The scaling factor of 20 produced values that were within 1Nm of the actual calculated values and therefore was considered to provide scaled data that had an acceptable measurement error.
5.5.5 Validation of the rig to measure stiffness

Stiffness was defined as “the amount of torque required to produce a given angular displacement”, the aim of this third pilot study was to validate the stiffness calculated from the system output against a known stiffness.

5.5.5.1 Methods

A set of springs with known stiffness were used to provide resistance as the rig arm was slowly moved from $0^\circ - 90^\circ - 0^\circ$. All the forces acting on the system were modelled and estimated.

Figure 5.9 shows the starting position of the rig arm and spring..

![Figure 5.9 Starting position of the rig arm and applied spring](image)

CoR = centre of rotation of rig arm

$r$ = distance from centre of rotation of rig arm to spring attachment

$L$ = original length of spring

$\beta$ = angle between spring and rig arm

$A$ = theoretical distance between centre of rotation of the rig and the spring attachment

---

113
The distances $r$ and $L$ were measured with a measuring tape and $\beta$ was measured with a universal goniometer. Using the cosine rule:

$$A^2 = r^2 + L^2 - 2rL \cos \beta$$

Equation 5.5

Followed by the sine rule:

$$\frac{A}{\sin \beta} = \frac{L}{\sin \alpha}$$

Equation 5.6

The value of $\alpha$ (Figure 5.9) was calculated.

Figure 5.10 shows the rig having undergone displacement $\Theta$ (as measured by the electrogoniometer)

![Diagram](image)

Figure 5.10 The rig arm having undergone displacement $\theta$ against spring $L$.  

$r$ has not changed

$A$ has not changed

$L_1$ = new length of spring

$l$ = insertion of spring
As r, A and α did not change and θ was the angle through which the rig arm moved, indicated by the electrogoniometer. Using Equation 5.6, the new length of the extended spring (L₁) could be calculated.

\[ L₁^2 = r^2 + A^2 - 2ra \cos(\theta + \alpha) \]  
Equation 5.7

Thus the extension of the spring could be calculated:

\[ \text{Extension of spring} = L₁ - L. \]  
Equation 5.8

Spring theory (Hookes Law) states that:

\[ F = kx \]  
Equation 5.9

Where F = force, k = the stiffness coefficient of the spring, and x = extension of the spring. Therefore the next step was to determine the force applied to extend the spring.

The torque transducer measured the total torque applied to the rig. As the system was in static equilibrium at each angle, the total torque (TT) could be described as:

\[ \text{TT} = \text{torque due to mass of rig} + \text{torque due to spring.} \]  
Equation 5.10

The torque due to the mass of the rig was estimated using polynomial equation (obtained from moving the unweighted rig through range of motion) and thus the measured torque due to spring force was determined. As the spring force (Fs) was not applied at 90° to the rig arm, (once the rig arm had been rotated) the force could be said to have both rotatory (Fx) and compressive (Fy) components (Figure 5.11).
Figure 5.11 X- and y components of the spring force ($F_s$)

Thus the torque applied to the rig arm due to spring was calculated as:

$$\text{Spring torque} = F_x r$$

Equation 5.11

Using equation 5.10 and 5.11 $F_x$ was estimated as:

$$F_x = \frac{T_T - (0.0003\theta^2 + 0.515\theta + 0.7661)}{r}$$

Where the polynormal equation represents the torque due to the weight of the rig and $\theta$ = displacement of the rig arm as measured by the electrogoniometer.

$F_x$ was determined as:

$$F_x = \sin \gamma F_s$$
Therefore the force required to extend the spring \((F_s)\) at any given angle could be determined.

The ability of the system to measure stiffness was determined by graphing the spring force against spring extension and using linear regression to determine the slope of the line. This stiffness value was compared against the known stiffness of the spring.

Six springs with differing stiffness’s were used and each spring was measured 3 times.

5.5.5.2 Results

Linear regression was undertaken on each set of data to determine the slope of the line (stiffness). Table 5.8 outlines the slope of the line (regression equation constant) relating the applied force and resulting extension for each trial. The slope of the line indicates the predicted spring stiffness and this was compared with the actual spring stiffness.

Table 5.8 Regression equation constants for each trial and the actual spring stiffness.

<table>
<thead>
<tr>
<th>Spring</th>
<th>Trial 1</th>
<th>Trial 2</th>
<th>Trial 3</th>
<th>Mean</th>
<th>Actual</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>37.018</td>
<td>41.583</td>
<td>42.792</td>
<td>40.464</td>
<td>39.085</td>
</tr>
<tr>
<td>2</td>
<td>19.832</td>
<td>18.728</td>
<td>20.061</td>
<td>19.540</td>
<td>20.014</td>
</tr>
<tr>
<td>3</td>
<td>101.49</td>
<td>105.52</td>
<td>101.75</td>
<td>102.920</td>
<td>96.657</td>
</tr>
<tr>
<td>4</td>
<td>96.131</td>
<td>100.53</td>
<td>86.036</td>
<td>94.232</td>
<td>91.684</td>
</tr>
<tr>
<td>5</td>
<td>115.800</td>
<td>112.530</td>
<td>124.360</td>
<td>117.563</td>
<td>119.71</td>
</tr>
<tr>
<td>6</td>
<td>141.77</td>
<td>160.5</td>
<td>134.39</td>
<td>145.563</td>
<td>145.46</td>
</tr>
</tbody>
</table>
In order to determine the reliability of the system to measure a known stiffness, an intra-class correlation coefficient was calculated on the three trials (ICC (3,1) = 0.993, 95% CI 0.956 – 1.000).

The correlation between the calculated stiffness and the actual stiffness was 0.996. From this the SEM was calculated as 2.97N. George, Batterham, & Sullivan (2000) suggested that linear regression with analysis of the slope of the line and the y-intercept could provide a useful method for determination of the agreement between two variables in small samples. The linear regression equation for the calculated stiffness and actual stiffness was calculated stiffness = (actual stiffness x 0.999) + 1.89. If the two variables are in perfect agreement, the slope of the line will be 1 and the intercept 0. Here the slope was 1 but the intercept was 1.89 suggesting that the calculated stiffness overestimated the actual stiffness by 1.89N/degree. The 95% confidence interval for the intercept was -9.24 – 13.02. As this CI contained 0, it could be reasoned that there was no significant bias in the calculation of stiffness by the stiffness rig and validity of the rig to calculate stiffness can be assumed.

5.5.6 Alignment of knee joint and measurement rig

The most common axis used to describe knee flexion/extension is the transepicondylar axis which is defined as the axis connecting the most prominent points on the lateral and medial condyles (Churchill et al, 1998; Most et al, 2004). One of the assumptions of the biomechanical model was that the axis of rotation of the knee joint remained aligned with the centre of rotation of the measurement rig at all times. However, the position of the transepicondylar axis changes as the knee moves through flexion and extension, with the most movement occurring at the
lateral condyle (up to 19mm posteriorly) (Dennis et al, 2003). As described in other studies, it was proposed to use the lateral epicondyle as an approximation of the flexion/extension axis. The aim of this pilot study was therefore to determine how well the lateral epicondyle remained aligned with the centre of rotation of the measurement rig during passive knee flexion/extension.

5.5.6.1 Methods

A VICON motion analysis system was used to track the position of a marker placed over the lateral epicondyle of the knee and also on the centre of the axis of rotation of the measurement rig. A single subject was measured. Co-ordinates in the antero-posterior and vertical direction were analysed over three trials.

5.5.6.2 Results

The maximum distance between the two markers in each of the three trials is given in Table 5.9.

Table 5.9 Maximum distance between lateral epicondylar marker and the rig arm marker

<table>
<thead>
<tr>
<th>Trial</th>
<th>AP direction (mm)</th>
<th>Vertical direction (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>14.4</td>
<td>51.1</td>
</tr>
<tr>
<td>2</td>
<td>15.5</td>
<td>50.0</td>
</tr>
<tr>
<td>3</td>
<td>17.1</td>
<td>51.5</td>
</tr>
</tbody>
</table>

5.5.6.3 Discussion

The variation in AP distance between the markers is within the 19 mm limits of AP translation reported by Dennis et al (2003) and also within the 60mm AP translation limit proposed by Crosier (2005). Several studies (Cappozzo et al., 1996; Fuller et
al., 1997; Holden et al., 1997) have also shown that skin mounted markers can show as much as 20mm of displacement during flexion/extension activities. Thus the difference in alignment seen between the static rig mounted marker and the skin-mounted marker could be attributed to skin movement.

Using anthropometry and trigonometry to calculate the lever arm and the therefore the overall torque due to the mass of the shank & foot (S & F), it was calculated that for a 1.7 m high, 70kg individual at 45° knee flexion, the torque due to the S & F would be 6.5 Nm. If the centre of rotation of the knee moved 50mm superiorly, this torque would be reduced to 3.5 Nm.

5.5.7 Reliability of angular velocity of passive motion

The system utilised a lever arm, manipulated by the researcher, in order to flex and extend the knee passively. As discussed in section 2.4.4.4 velocity can influence the response of the tissues to displacement. Therefore the aim of this pilot study was to establish the reliability of the researcher to provide a consistent passive motion.

5.5.7.1 Methods

Six healthy volunteers were took part in a test to determine the intra- and inter-day reliability of the velocity of the passive motion. Each subject was tested 3 times on each of two days. The subject was attached to the stiffness rig, taking care to align the lateral femoral epicondyle with the axis of rotation of the rig. The foot was strapped to the footplate and an electrogoniometer attached over the knee joint. The arms of the electrogoniometer were aligned with the long axes of the femur (greater trochanter to lateral femoral epicondyle) and the lower limb (head of fibula to the lateral malleolus). On each day 5 cycles of both flexion and extension were
undertaken at a slow, medium and fast velocity. These speeds were selected by the researcher. The output from the electrogoniometer was recorded and scaled as described in previous sections. The displacement data was graphed against time and each cycle identified by time points. Linear regression was used to determine the slope of the line of displacement vs time for each cycle. The mean value over each of the 5 cycles of flexion and extension at each speed were calculated for every subject.

5.5.7.2 Results

The mean and sd of the angular velocity at each speed, for each day are shown in Table 5.10.

<table>
<thead>
<tr>
<th>Angular Velocity</th>
<th>Day 1</th>
<th>Day 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (sd)</td>
<td>Mean (sd)</td>
</tr>
<tr>
<td><strong>Flexion</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Slow</td>
<td>7.9°/s (1.2)</td>
<td>7.0°/s (0.7)</td>
</tr>
<tr>
<td>Medium</td>
<td>21.6°/s (4.8)</td>
<td>24.9°/s (7.0)</td>
</tr>
<tr>
<td>Fast</td>
<td>118.3°/s (12.0)</td>
<td>115.5°/s (14.6)</td>
</tr>
<tr>
<td><strong>Extension</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Slow</td>
<td>6.8°/s (0.9)</td>
<td>6.4°/s (0.7)</td>
</tr>
<tr>
<td>Medium</td>
<td>21.2°/s (4.9)</td>
<td>27.3°/s (6.6)</td>
</tr>
<tr>
<td>Fast</td>
<td>118.5°/s (15.3)</td>
<td>114.9°/s (25.1)</td>
</tr>
</tbody>
</table>

Intra-class correlation coefficients were strongly influenced by the between subject variance (low between subject variance results in low ICC’s), and as the aim of this pilot was to have both low inter- and low intra subject variance, it was considered
that ICC’s were not the most appropriate method of establishing reliability. The standard error of measurement (SEM) was therefore calculated (Hopkins, 2000). The SEM represented the error in velocity over the five trials within each day and within each velocity (Table 5.11).

Table 5.11: Intra-trial error for fast and slow velocity

<table>
<thead>
<tr>
<th>Day 1</th>
<th>Day 2</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Flexion</strong></td>
<td></td>
</tr>
<tr>
<td>Slow</td>
<td>0.6</td>
</tr>
<tr>
<td>Medium</td>
<td>3.5</td>
</tr>
<tr>
<td>Fast</td>
<td>7.1</td>
</tr>
<tr>
<td><strong>Extension</strong></td>
<td></td>
</tr>
<tr>
<td>Slow</td>
<td>0.6</td>
</tr>
<tr>
<td>Medium</td>
<td>3.5</td>
</tr>
<tr>
<td>Fast</td>
<td>7.4</td>
</tr>
</tbody>
</table>

The SEM indicate that the typical error associated with a slow velocity is approximately 0.6 °/s, with a mean angular velocity of approximately 7°/s. The medium velocity showed more variability, particularly in flexion where the typical error was 3.5 °/s with a mean angular velocity of approximately 21°/s. The fast velocity had a maximum error of 12 °/s in approximately 115 °/s.

Other studies have measured stiffness at velocities of 0.078 rad/s (4.47 °/s) up to 0.2 rad/s (11.46 °/s) but did not consider the reliability of the angular velocity. Angular motion of the lower limb has been reported as high as 6.5 rad/s (376°/s) during the swing phase of gait, with typical values of around 2.8 rad/s (159°/s) during sit-stand.
As differences in resistive torque had been found at other joints, at speeds as low as 25°/s, it was proposed to utilise both the slow and fast speeds during this study.

5.5.8 Optimal sampling frequency

As discussed in section 5.2.6.1, sampling frequency theory states that the sampling frequency should be twice that of the signal although it has been recommended that 4 times the signal frequency should be used.

Following the results reported section 5.5.7, the optimal sampling frequency required to capture data for every degree of angular displacement at the chosen angular velocities is shown in Table 5.12.

Table 5.12 Recommended sampling frequencies for chosen angular velocities

<table>
<thead>
<tr>
<th>Speed</th>
<th>Freq according to theory</th>
<th>Recommended frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>7°/s</td>
<td>14°/s</td>
<td>28°/s</td>
</tr>
<tr>
<td>115°/s</td>
<td>230°/s</td>
<td>460°/s</td>
</tr>
</tbody>
</table>

These values assumed that it was desirable to capture every degree of angular displacement. In order to determine empirically whether reducing the sampling frequency had a detrimental effect on the quality of the data, the angular displacement data from the pilot study in section 5.5.7 was explored.

5.5.8.1 Methods

Data was originally collected from both the electrogoniometer (angular displacement) and the stiffness rig (torque) at 100Hz. It was then further processed
so that every second data point was extracted (to mimic a sampling frequency of 50Hz) and every 4th data point was extracted (to mimic a sampling frequency of 25Hz). Table 5.13 gives an example using displacement data to illustrate.

Table 5.13 Illustration of data used to mimic a 50Hz and a 25Hz sampling frequency.

<table>
<thead>
<tr>
<th>Data point</th>
<th>measured 100Hz</th>
<th>estimated 50Hz</th>
<th>estimated 25Hz</th>
</tr>
</thead>
<tbody>
<tr>
<td>P1</td>
<td>76</td>
<td>76</td>
<td>76</td>
</tr>
<tr>
<td>P2</td>
<td>77</td>
<td></td>
<td></td>
</tr>
<tr>
<td>P3</td>
<td>79</td>
<td>79</td>
<td></td>
</tr>
<tr>
<td>P4</td>
<td>82</td>
<td></td>
<td>82</td>
</tr>
</tbody>
</table>

Torque-displacement graphs at each of the frequencies were plotted in order to visually compare differences between in frequencies.

The average of P1 and P3 (data used to create a 50Hz frequency) was then compared with P2 in order to determine whether there was any significant difference between data collected at 100Hz and that which would have been collected at 50Hz. Figure 5.12 illustrates how these differences might influence the data.
Figure 5.12 Illustration of differences in sampling frequency.

The mean difference (and 95% confidence intervals) between the measured data point at 100Hz and the average over each flex-extension cycle collected during the first session was calculated for each subject. Confidence intervals were calculated using the formula $\mu = \bar{x} \pm 1.96(SE_M)$ and where $SE_M = \frac{SD}{\sqrt{N}}$.

5.5.8.2 Results

A sample graph is provided in Figure 5.13. All three sampling frequencies followed exactly the same shape suggesting that 25Hz was sufficient to capture motion at the slow velocity.
The graphs also demonstrated that sampling at 25Hz even at fast speeds resulted in no deterioration of the data, compared to sampling at 100Hz. Sampling at 25 Hz, when the angular velocity was around 115°/s resulted in a capture of data at least every 4.6° (calculated by dividing 115 by 25). At the faster speed, linear regression showed the rate of change of torque by degree to be between 0.21Nm and 0.33Nm. Thus a 25Hz sampling frequency which captured displacement every 4.6°, would capture a rate of change of torque of around 1Nm.

In order to explore the data further and to support the above conclusion statistically, the mean difference between the 100Hz measured data and the estimated 50Hz, 25Hz and 10Hz data was calculated over each trial by each subject. The following table
(Table 5.14) indicates the mean difference in the displacement data between the 100Hz data point and the estimated equivalent from the estimated 50Hz, 25Hz and 10Hz data. Data is presented for both slow and fast speeds.

Table 5.14 Mean difference in displacement data between sampling frequencies of 100Hz and 50Hz, 25Hz and 10Hz.

<table>
<thead>
<tr>
<th>Difference</th>
<th>Subject 1</th>
<th>Subject 2</th>
<th>Subject 3</th>
<th>Subject 4</th>
<th>Subject 5</th>
<th>Subject 6</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Average absolute mean difference (degrees)</td>
<td>(95% CI)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>slow</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>100Hz vs 50Hz</td>
<td>0.0010 (0.0010, 0.0010)</td>
<td>0.0013 (0.0012, 0.0014)</td>
<td>0.0013 (0.0012, 0.0013)</td>
<td>0.0045 (0.0044, 0.0046)</td>
<td>0.0000 (0.0000, 0.0002)</td>
<td>0.0000 (0.0000, 0.0001)</td>
</tr>
<tr>
<td>100Hz vs 25Hz</td>
<td>0.0038 (0.0036, 0.0040)</td>
<td>0.0051 (0.0047, 0.0055)</td>
<td>0.0049 (0.0046, 0.0052)</td>
<td>0.0160 (0.0155, 0.0165)</td>
<td>0.0003 (-0.0001, 0.0007)</td>
<td>0.0002 (-0.0001, 0.0005)</td>
</tr>
<tr>
<td>100Hz vs 10Hz</td>
<td>0.0227 (0.0209, 0.0245)</td>
<td>0.0304 (0.0270, 0.0339)</td>
<td>0.0293 (0.0263, 0.0324)</td>
<td>0.0618 (0.0587, 0.0649)</td>
<td>0.0020 (-0.0021, 0.0062)</td>
<td>0.0013 (-0.0017, 0.0042)</td>
</tr>
<tr>
<td><strong>fast</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>100Hz vs 50Hz</td>
<td>0.0104 (0.0099, 0.0110)</td>
<td>0.0144 (0.0135, 0.0153)</td>
<td>0.0127 (0.0119, 0.0135)</td>
<td>0.0126 (0.0119, 0.0132)</td>
<td>0.0006 (-0.0009, 0.0020)</td>
<td>0.0004 (-0.0004, 0.0013)</td>
</tr>
<tr>
<td>100Hz vs 25Hz</td>
<td>0.0416 (0.0384, 0.0447)</td>
<td>0.0574 (0.0522, 0.0625)</td>
<td>0.0507 (0.0460, 0.0553)</td>
<td>0.0490 (0.0453, 0.0527)</td>
<td>0.0024 (-0.0060, 0.0107)</td>
<td>0.0018 (-0.0029, 0.0065)</td>
</tr>
<tr>
<td>100Hz vs 10Hz</td>
<td>0.2584 (0.2275, 0.2893)</td>
<td>0.3524 (0.3039, 0.4008)</td>
<td>0.3155 (0.2686, 0.3624)</td>
<td>0.2935 (0.2599, 0.3269)</td>
<td>0.4229 (0.3715, 0.4742)</td>
<td>0.2948 (0.2648, 0.3247)</td>
</tr>
</tbody>
</table>

The data above demonstrated that the differences in displacement data between the measured 100Hz data and the estimated 50Hz and 25Hz data were less than 1/100th of a degree. The confidence intervals include zero suggesting that there was no
significant difference between the data sets and confirming that no significant data points would be missed by collecting at either 50Hz or 25Hz. This data corroborates that seen in the displacement torque graphs and supports the conclusion that 25Hz would be sufficient for the capture of this displacement data.

The following table (Table 5.15) presents differences in torque data between the measured 100Hz and the estimated 50Hz and 25Hz data.

Table 5.15 Mean difference in torque data between sampling frequencies of 100Hz and 50Hz, 25Hz and 10Hz.

<table>
<thead>
<tr>
<th>Difference</th>
<th>Subject 1</th>
<th>Subject 2</th>
<th>Subject 3</th>
<th>Subject 4</th>
<th>Subject 5</th>
<th>Subject 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>slow</td>
<td>Average mean difference (Nm)</td>
<td>(95% CI)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>100Hz vs 50Hz</td>
<td>&lt;0.0001 (0.0000, 0.0000)</td>
<td>&lt;0.0001 (0.0000, 0.0000)</td>
<td>0.0001 (0.0000, 0.0000)</td>
<td>&lt;0.0001 (0.0000, 0.0000)</td>
<td>&lt;0.0001 (0.0000, 0.0000)</td>
<td>&lt;0.0001 (0.0000, 0.0000)</td>
</tr>
<tr>
<td>100Hz vs 25Hz</td>
<td>&lt;0.0001 (0.0000, 0.0000)</td>
<td>&lt;0.0001 (0.0000, 0.0000)</td>
<td>&lt;0.0001 (0.0000, 0.0000)</td>
<td>&lt;0.0001 (-0.0002, 0.0002)</td>
<td>&lt;0.0001 (0.0000, 0.0000)</td>
<td>&lt;0.0001 (0.0000, 0.0000)</td>
</tr>
<tr>
<td>fast</td>
<td>Average mean difference (Nm)</td>
<td>(95% CI)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>100Hz vs 50Hz</td>
<td>&lt;0.0001 (-0.0002, 0.0001)</td>
<td>&lt;0.0001 (-0.0003, 0.0003)</td>
<td>&lt;0.0001 (-0.0003, 0.0003)</td>
<td>&lt;0.0001 (-0.0003, 0.0003)</td>
<td>&lt;0.0001 (-0.0003, 0.0003)</td>
<td>&lt;0.0001 (-0.0003, 0.0003)</td>
</tr>
<tr>
<td>100Hz vs 25Hz</td>
<td>&lt;0.0001 (-1.9595, 0.0010)</td>
<td>&lt;0.0001 (-0.0016, 0.0015)</td>
<td>0.0017 (-0.0017, 0.0017)</td>
<td>&lt;0.0001 (-0.0016, 0.0015)</td>
<td>&lt;0.0001 (-0.0018, 0.0018)</td>
<td>&lt;0.0001 (-0.0007, 0.0006)</td>
</tr>
</tbody>
</table>

The torque data showed similar results to the displacement in that there was no significant difference between the measured 100Hz data and that which it was estimated would have been collected at 50Hz or 25Hz. It is unlikely that any significant data points would have been missed if the data had been collected at these lower frequencies.
5.5.8.3 Fourier Analysis

All of the signals were made up of several signals at varying frequencies. Stergiou, (2004) notes that a ‘true’ signal has a steady state whereas noise has random varying frequency and amplitude. In order to separate the noise from the ‘true’ signal it was necessary to filter out the noise. One way in which noise could be filtered out was by the selection of an appropriate sampling frequency. The second was by application of an appropriate filter. Fourier analysis was one way in which the various frequencies within a signal could be determined. The results of the Fourier analysis could be used set the sampling frequency and to select an appropriate filter.

A sample of both slow and fast velocity displacement data was analysed using Fast Fourier Transform techniques (MatLab\textsuperscript{15}). The resulting plots are shown below (Figure 5.14 and Figure 5.15).

\textsuperscript{15} The Mathworks Inc., Natick, Massachusetts
Figure 5.14 Frequency plot of the displacement signal frequency at a slow speed

Figure 5.15 Frequency plot of the displacement signal frequency at a fast speed
The plots show the distribution of the signals within the data, by frequency. The majority of the signal occurred under 1Hz in both the fast and slow data. Using the Nyquist-Shannon sampling frequency rule as described in section 5.2.6.1, a sampling frequency of only 2Hz should be sufficient to capture the true signal. However in practice, biomechanical data is most often collected at much higher frequencies (Stergiou, 2004) and therefore a frequency of 50Hz was chosen.

5.5.9 Reliability of stiffness calculations

The purpose of this final pilot study was to develop the application of the system to testing of stiffness in a human knee and to determine the reliability of the measurements. The previous pilot studies have determined that the system can reliably measure both torque and displacement as well as reliably determining stiffness of a known material (section 5.5.5). Application of the system to a human joint however introduced a number of potential sources of variation – alignment of the centre of rotation, skin movement and placement of the electrogoniometer as well as inability of the participant to relax sufficiently for knee flexion/extension to be passive. This pilot study aimed to determine the intra- and inter day reliability of the measurements in-vivo.

5.5.9.1 Methods

Six participants underwent the stiffness assessment procedure using the torque transducer rig and the electrogoniometer. Participants were dressed in shorts and barefoot. The electrogoniometer was attached over the lateral aspect of the knee joint along the long axes of the thigh and shank. Subjects were then seated on a plinth with the legs hanging over the edge. The left foot was placed on a stool, the lateral
epicondyle of the right knee was aligned with the axis of rotation of the torque transducer rig using observation and the foot strapped to the foot plate. The foot plate was adjusted so that the knee remained aligned with the axis of rotation throughout flexion/extension. Each participant was instructed to relax and allow the researcher to flex and extend the knee passively. Five cycles of both flexion and extension were undertaken at both slow and fast velocities. The test was repeated a week later.

Passive resistance to motion was calculated according to the equation outlined in chapter 3. A MatLab\textsuperscript{16} programme was written which allowed the researcher to divide the dataset into individual flexion and extension cycles. The passive resistance to motion was then plotted against angular displacement and the MatLab programme then allowed the researcher to determine 3 phases within each cycle (flexion, mid-range and extension). The slope of the line relating passive resistance to motion and angular displacement was then calculated for each phase in each cycle using the MatLab programme. This provided 6 measures of stiffness per flexion-extension cycle (3 values as the knee was flexed and 3 values as the knee was extended).

Data from the middle 3 flexion-extension cycles was analysed using SPSS v16. The flexion phase stiffness was considered to be most relevant during knee flexion and conversely that extension phase stiffness was most relevant as the knee was extended.

Intra-class correlation coefficients were used to determine intra-day (model 3,1) and inter-day (3,3) reliability. Intra-day reliability was determined from the 3 cycles

\textsuperscript{16} The Mathworks Inc, Massachusetts
analysed. Inter-day reliability was calculated by taking the average of day 1 and comparing with the average of day 2.

5.5.9.2 Results

Flexion, extension and mid-range stiffness at both slow and fast velocities were calculated.

Table 5.16 shows the mean values for flexion stiffness each subject for each day and the intra-day ICC. Flexion stiffness at a slow speed showed good-excellent intra-day reliability (Table 5.16), agreement between day 1 and day 2 was calculated in order to establish inter-day reliability (ICC (3,3) =-0.794). This ICC suggested a negative relationship between the two variables indicating poor agreement between days.

Table 5.16 Flexion phase stiffness at slow velocity

<table>
<thead>
<tr>
<th>Subject</th>
<th>Day 1 mean (sd)</th>
<th>Day 2 mean (sd)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Flexion stiffness</td>
<td>Flexion stiffness</td>
</tr>
<tr>
<td>1</td>
<td>0.248 (0.050)</td>
<td>0.216 (0.100)</td>
</tr>
<tr>
<td>2</td>
<td>0.440 (0.132)</td>
<td>-0.069 (0.010)</td>
</tr>
<tr>
<td>3</td>
<td>0.236 (0.010)</td>
<td>0.158 (0.056)</td>
</tr>
<tr>
<td>4</td>
<td>0.643 (0.203)</td>
<td>-0.0452 (0.068)</td>
</tr>
<tr>
<td>5</td>
<td>0.407 (0.052)</td>
<td>0.457 (0.144)</td>
</tr>
<tr>
<td>ICC (3,1)</td>
<td>0.639</td>
<td>0.847</td>
</tr>
</tbody>
</table>
Table 5.17 shows the mean extension phase stiffness for each subject for each day. Day 1 showed moderate agreement (ICC = 0.464) and day 2 showed poor agreement (ICC = -0.245). The inter-day reliability also showed poor agreement (ICC (3,3) = -0.181).

Table 5.17 Extension phase stiffness at slow velocity

<table>
<thead>
<tr>
<th>Subject</th>
<th>Day 1 mean (sd)</th>
<th>Day 2 mean (sd)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Extension stiffness</td>
<td>Extension stiffness</td>
</tr>
<tr>
<td>1</td>
<td>0.484 (0.098)</td>
<td>0.226 (0.078)</td>
</tr>
<tr>
<td>2</td>
<td>0.243 (0.015)</td>
<td>0.225 (0.027)</td>
</tr>
<tr>
<td>3</td>
<td>0.264 (0.090)</td>
<td>0.232 (0.020)</td>
</tr>
<tr>
<td>4</td>
<td>0.370 (0.135)</td>
<td>0.216 (0.080)</td>
</tr>
<tr>
<td>5</td>
<td>0.291 (0.065)</td>
<td>0.279 (0.095)</td>
</tr>
<tr>
<td>ICC</td>
<td>0.464</td>
<td>-0.245</td>
</tr>
</tbody>
</table>

Table 5.18 shows the mid-range stiffness values for each subject for each day at slow velocity. Within day1 reliability was good (ICC = 0.845) and moderate for day 2 (ICC = 0.473). Inter-day reliability (3,3) was determined as good (ICC = 0.771).
Table 5.18 Mid-range stiffness at slow velocity

<table>
<thead>
<tr>
<th>Subject (mid range)</th>
<th>Midrange stiffness Day 1 mean (sd)</th>
<th>Midrange stiffness Day 2 mean (sd)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>-0.012</td>
<td>0.022</td>
</tr>
<tr>
<td>2</td>
<td>0.007</td>
<td>0.018</td>
</tr>
<tr>
<td>3</td>
<td>0.027</td>
<td>0.02</td>
</tr>
<tr>
<td>4</td>
<td>0.088</td>
<td>0.054</td>
</tr>
<tr>
<td>5</td>
<td>-0.029</td>
<td>-0.038</td>
</tr>
<tr>
<td>ICC (3,1)</td>
<td>0.845</td>
<td>0.473</td>
</tr>
</tbody>
</table>

Flexion stiffness at fast velocity is shown in Table 5.19. Intra day reliability for fast flexion stiffness was good. The inter-day ICC was poor (ICC (3,3) = 0.242, -1.712 to 0.886, p = 0.340).

Table 5.19 Flexion stiffness at fast velocity

<table>
<thead>
<tr>
<th>Subject</th>
<th>Day 1 mean (sd)</th>
<th>Day 2 mean (sd)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0.532</td>
<td>0.468</td>
</tr>
<tr>
<td>2</td>
<td>0.425</td>
<td>0.296</td>
</tr>
<tr>
<td>3</td>
<td>0.204</td>
<td>0.227</td>
</tr>
<tr>
<td>4</td>
<td>2.228</td>
<td>0.415</td>
</tr>
<tr>
<td>5</td>
<td>0.210</td>
<td>0.243</td>
</tr>
<tr>
<td>6</td>
<td>0.493</td>
<td>-0.211</td>
</tr>
<tr>
<td>ICC (3,1)</td>
<td>0.784</td>
<td>0.667</td>
</tr>
</tbody>
</table>
Mid-range stiffness at fast velocity showed poor intra-day reliability for day 1 and good reliability for day 2 (Table 5.20). Inter-day reliability was moderate (ICC (3,3) = 0.502, -1.772 to 0.928, p = 0.225).

Table 5.20 Mid-range stiffness at fast velocity

<table>
<thead>
<tr>
<th>Subject</th>
<th>Day 1 mean (sd)</th>
<th>Day 2 mean (sd)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>-0.066</td>
<td>-0.142</td>
</tr>
<tr>
<td>2</td>
<td>-0.041</td>
<td>-0.055</td>
</tr>
<tr>
<td>3</td>
<td>-0.063</td>
<td>-0.161</td>
</tr>
<tr>
<td>4</td>
<td>-0.055</td>
<td>0.033</td>
</tr>
<tr>
<td>5</td>
<td>-0.094</td>
<td>-0.215</td>
</tr>
<tr>
<td>6</td>
<td>-0.148</td>
<td>-0.140</td>
</tr>
<tr>
<td>ICC (3,1)</td>
<td>0.325</td>
<td>0.756</td>
</tr>
</tbody>
</table>

Intra-day reliability for fast extension stiffness was acceptable on day 1 (ICC = 0.743) but low on day 2 (ICC= 0.294) (Table 5.21). Inter-day reliability was very poor (ICC (3,3) = -17.118, 7.115 to 0.382).
Table 5.21 Extension stiffness at fast velocity

<table>
<thead>
<tr>
<th>Subject</th>
<th>Day 1 mean (sd)</th>
<th>Day 2 mean (sd)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0.757</td>
<td>0.792</td>
</tr>
<tr>
<td>2</td>
<td>0.745</td>
<td>0.441</td>
</tr>
<tr>
<td>3</td>
<td>0.709</td>
<td>0.845</td>
</tr>
<tr>
<td>4</td>
<td>1.764</td>
<td>0.456</td>
</tr>
<tr>
<td>5</td>
<td>0.455</td>
<td>0.875</td>
</tr>
<tr>
<td>6</td>
<td>0.048</td>
<td>1.210</td>
</tr>
<tr>
<td>ICC (3,1)</td>
<td>0.743</td>
<td>0.294</td>
</tr>
</tbody>
</table>

Intra-day reliability for the stiffness variables was in general within acceptable limits. Inter-day reliability was poor. The previous pilot studies had shown that inter-day reliability of the electrogoniometer and the torque transducer to be good, suggesting that the source of the variance was the participants. Previous work has indicated considerable intra-subject variance and the results of this pilot study highlight that subject testing should be completed in a single day.

5.5.10 Pilot study conclusions

Table 5.22 summarises the main conclusions from the pilot studies.
Table 5.22 Summary of pilot study conclusions

<table>
<thead>
<tr>
<th>Pilot</th>
<th>Aims</th>
<th>Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Establish scaling data for the electrogoniometer and establish reliability</td>
<td>Good inter-session reliability. Degrees = 40.112volts + 4.254.</td>
</tr>
<tr>
<td>2</td>
<td>Confirm validity of the scaling data provided for the torque transducer</td>
<td>Scaling data provided by manufacturer was appropriate.</td>
</tr>
<tr>
<td>3</td>
<td>Establish validity of the system to measure stiffness</td>
<td>Excellent agreement between known stiffness and calculated stiffness. No significant bias and thus validity was assumed.</td>
</tr>
<tr>
<td>4</td>
<td>Explore alignment of the knee and centre of rotation of the measurement rig</td>
<td>Knee and centre of rotation of the measurement rig remained aligned within less than 2cm.</td>
</tr>
<tr>
<td>5</td>
<td>Determine intra-rater reliability of the velocity of passive motion</td>
<td>Measurement error less than 1° per second at slow speeds (around 7° per second) and 12°/s at fast speeds (approx 115°/sec). Errors considered within acceptable limits.</td>
</tr>
<tr>
<td>6</td>
<td>Identify the optimal sampling frequency</td>
<td>A sampling frequency of 25Hz was sufficient to capture significant events.</td>
</tr>
<tr>
<td>7</td>
<td>Intra and inter day reliability of stiffness data</td>
<td>Intra-day reliability was good but considerable intra-subject variance seen between days resulting in low inter-day reliability.</td>
</tr>
</tbody>
</table>
6 Methods

This chapter describes the clinical tests that were designed in order to address the objectives and hypotheses outlined in Chapter 3. Outlined are the study design, ethical considerations, subjects, sampling methods, outcome measures and testing procedure. Finally, the methods of data analysis are described.

6.1 Study design

The study was divided into two parts. The first part of the study addressed the second and third objectives of the study and utilised a case control design with three groups – a group of participants with OA, a group who were 1 year post-TKA and a group of age matched healthy controls. This part of the study was considered as exploratory with the intention of providing data on which to base future studies. The second part of the study was designed specifically to address the fourth objective and involved comparisons between a group of patients who were scheduled to undergo primary TKA for OA and a group who were 1 year post-TKA.

6.2 Ethical considerations

Ethical approval to carry out the study on NHS patients was given by Lothian local research ethics committee (LREC) in June 2006. A substantial amendment to the section of the protocol dealing with the target population for the control group was approved by Lothian LREC in October 2006. No major ethical issues were identified.

Management approval to carry out the study (and the subsequent amendment) on NHS Lothian, University Hospitals Division property was given by NHS Lothian
Research and Development Office in October 2006. An honorary contract was also given by NHS Lothian in order to allow the researcher to work on NHS property.

In order to ensure participant anonymity and to comply with data protection, all participants were allocated a unique code which was used to identify study data. All paper data was stored in a locked filing cabinet. All electronic data was collected on a password protected laptop and then transferred to a password protected secure server.

6.3 Pilot work

A pilot study to determine the intra-rater reliability of the researcher with respect to the timed tests of function was carried out prior to commencement of the first part of the main study (Appendix 2).

Table 6.1 Intra-rater reliability for timed tests

<table>
<thead>
<tr>
<th>Test</th>
<th>ICC (model (3,1))</th>
<th>95% Standard error of measurement (in seconds)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Timed Up and Go</td>
<td>0.8</td>
<td>0.8</td>
</tr>
<tr>
<td>Timed stair ascent/descent test</td>
<td>0.8</td>
<td>0.5</td>
</tr>
</tbody>
</table>

The results of the pilot (Table 6.1) showed that the researcher had excellent intra-rater reliability (Fleiss, 1986) and could demonstrate an intra-rater error of 0.8 of a second or less when timing these activities

6.4 Recruitment

Samples were taken from 3 different populations – those who were on the waiting list for TKA (OA group) and who were scheduled for surgery within 6 weeks, those
who had undergone surgery for TKA within the previous 10 – 14 months (TKA group) and an age matched control population. All potential participants received an information sheet and were given at least 1 week to consider this information before agreeing to take part in the study. All participants gave written consent to take part in the study.

6.4.1 TKA and OA group

Five consultant orthopaedic surgeons agreed to allow their patients to be approached to take part in the study.

In part 1 of the study patients who fulfilled the inclusion criteria for either the TKA or the OA group were sent an information sheet and invited them to take part. The letter was followed up with a phone call in order to allow any further questions to be addressed and to agree upon a suitable time to come in for testing. A sample size of n = 10 (OA group) and n = 30 (TKA group) was proposed.

In part 2 of the study, a further sample of patients who fulfilled the inclusion criteria for the OA and TKA groups were offered the opportunity to participate by completing the stiffness questionnaire only (Appendix 3). Those who fulfilled the inclusion criteria for the OA group were offered the stiffness questionnaire along with the routine audit questionnaire during their appointment at the pre-admission clinic. Those who fulfilled the inclusion criteria for the TKA group were identified from hospital audit data and sent an information sheet and stiffness questionnaire along with a consent form and stamped-addressed envelope. A two month time window was set for recruitment of participants to this phase and the subsequent sample size reflected all who volunteered to take part during this time period.
6.4.2 Control group

Participants for the control group were recruited from several local community groups. The leader of two local community groups agreed that the researcher could speak to the groups. A brief presentation regarding the study was made and information sheets handed out. Interested volunteers were invited to contact the researcher following the session either via telephone or email. These two groups failed to yield sufficient numbers and therefore information on the study was disseminated more widely via the Centre for the Older Persons Agenda (COPA) network at QMU. The study information sheet was sent out in electronic format to members of the COPA ‘Hub’ which was a group of older people (approximately n = 80) who had registered their interest in potentially taking part in research studies on issues that affect older people. Potential volunteers were again invited to contact the researcher by email or telephone. A sample size of n = 20 was proposed.

6.4.3 Inclusion/Exclusion criteria

All subjects were required to have the ability to complete the physical testing and were able to read/write sufficiently in order to complete the questionnaires. As some bias may be introduced if the researcher or clinician is required to complete the questionnaire for the subject (Lieberman et al, 1996), this criteria was deemed necessary. Subjects with neuromuscular conditions which might affect the tone of the muscles were excluded. It was necessary for the skin over the lower limb to be in good condition so that it would not be damaged by the removal of micropore tape and sticky electrodes and therefore subjects with poor skin or circulatory problems in
the lower limb were also excluded. Inclusion/exclusion criteria are detailed in Table 6.2.
Table 6.2 Inclusion/exclusion criteria

<table>
<thead>
<tr>
<th>Group</th>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control group</td>
<td>• Aged between 50 and 80 years</td>
<td>• Unable/unwilling to provide consent to take part</td>
</tr>
<tr>
<td></td>
<td>• Ability to complete the questionnaires</td>
<td>• Current musculoskeletal pathology at the hip, knee or ankle of the knee to be tested.</td>
</tr>
<tr>
<td></td>
<td>• Ability to complete the physical testing</td>
<td>• Circulatory problems in the lower limb of the knee to be tested</td>
</tr>
<tr>
<td></td>
<td>• Unable/unwilling to provide consent to take part</td>
<td>• History of neuromuscular disease*</td>
</tr>
<tr>
<td></td>
<td>• Current musculoskeletal pathology at the hip, knee or ankle of the knee to be tested.</td>
<td>• Skin problems such as eczema, infection, pressure sores or ulcers in the lower limb.</td>
</tr>
<tr>
<td></td>
<td>• Circulatory problems in the lower limb of the knee to be tested</td>
<td>• Allergies to micropore tape or sticking plasters</td>
</tr>
<tr>
<td></td>
<td>• History of neuromuscular disease*</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Skin problems such as eczema, infection, pressure sores or ulcers in the lower limb.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Allergies to micropore tape or sticking plasters</td>
<td></td>
</tr>
<tr>
<td>OA</td>
<td>• Scheduled to receive a primary TKA within 6 weeks of assessment</td>
<td>• Unwilling/unable to take part</td>
</tr>
<tr>
<td></td>
<td>• Primary diagnosis of osteoarthritis</td>
<td>• Circulatory problems in the lower limb</td>
</tr>
<tr>
<td></td>
<td>• Ability to complete the questionnaire</td>
<td>• History of neuromuscular disease</td>
</tr>
<tr>
<td></td>
<td>• Ability to complete the physical testing</td>
<td>• Skin problems such as eczema, infection, pressure sores or ulcers in the lower limb.</td>
</tr>
<tr>
<td></td>
<td>• Under the care of one of the 5 surgeons who agreed to inclusion of their patients in the study.</td>
<td>• Allergies to micropore or sticking plasters</td>
</tr>
</tbody>
</table>

* such as Parkinsons Disease, Multiple Sclerosis, CVA or cerebral palsy
6.5 Outcome measures and Instrumentation

This section outlines the primary outcomes measures and method of data collection.

All testing was undertaken in the Orthopaedics Outpatients department (OOPD) of the Royal Infirmary of Edinburgh at Little France. A dedicated research room was used which ensured privacy. Each test took approximately 60mins to complete.

6.5.1 Subject Demographics

The following data was obtained from patient medical records and through initial interview with the patient.

- Date of Birth – all groups
- Gender – all groups
- Affected side – OA and TKA groups
- Type of knee replacement – OA and TKA groups
- Complications – OA and TKA groups

6.5.2 Clinical knee examination

In order to provide data against which stiffness variables could be normalised, anthropometric data was collected as suggested by Heerkens (1985). The following data was collected:

- Height
- Weight
- Circumference of mid-thigh (at 50% of the length of thigh)
- Leg length (lateral knee joint line to lat. Malleolus)
- Thigh length (greater trochanter to lateral knee joint line)
Anthropometric data was collected using a standard stadiometer (height), scales, Vernier callipers and a measuring tape. A physical knee examination was then undertaken. This was similar to the format used by the American Knee Society in their collection of data for the Knee Society Score (Insall et al, 1989). Although it was not intended to calculate a Knee Society Score for the assessment of pain and function, it was felt that the Knee Subscore (Bach et al, 2002) was a useful way to create a standardised knee examination which would allow comparison of the dataset with the reported literature in order to determine how representative of the population the sample was. The following additional variables were noted.

- Knee effusion - assessed through the fluid displacement test (Petty & Moore, 2006)
- Manual muscle strength – assessed according to the Medical Research Council grading scale (Kendall, McCreary, & Provance, 1993)

6.5.3 Patient reported outcomes

Patient reported measures of pain, function and stiffness were gathered using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) (Bellamy, 2000). In addition a generic health measure, the SF-12 v.1 (Ware, Kosinski, & Keller, 1995) was used to assess mental and physical health status. These questionnaires have been shown to be valid, reliable and responsive in assessing outcomes following TKA (Bellamy et al, 1988; Kreibich et al, 1996; Parent & Moffat, 2002) and have been recommended to be used simultaneously. The SF-12 was routinely used by the Royal Infirmary of Edinburgh (RIE) as part of their
ongoing audit of patients pre- and post-joint arthroplasty and therefore where this data had already been provided for audit, it was obtained from audit records with the agreement of RIE and the patient.

Each participant also completed a visual analogue scale (VAS) for stiffness and the descriptors of stiffness (Appendix 3).

6.5.4 Objective measures of function

The Timed Up and Go (TUG) test, the 13-m walk test and a timed stair ascent test were administered as objective measures of function.

Figure 6.1 Stair and chair set-up for TUG and Stair ascent/descent test.
6.5.4.1 Timed Up and Go

For the TUG test, the protocol described by Freter and Fruchter (2000) was used. A standard chair of height 46cm (Figure 6.1) was placed with the front legs on a marker strip. Another marker strip was placed 3m away. Participants were given the instruction ‘when I say go, rise from the chair, walk to this line [the line was pointed out], cross the line, turn round and go back to the chair and sit down. Go at your normal speed and you may use the arms of the chair if necessary’. The stopwatch was started when the participants buttocks left the chair and stopped when they touched the chair upon sitting down again. The test was repeated 3 times. The test was timed in seconds (s).

6.5.4.2 Timed stair ascent/descent

The timed stair ascent/descent was undertaken using a standard set of stairs (Figure 6.1). The participant ascended 3 steps (riser height = 20cm) to the top and then descended 4 steps (riser height = 15cm) to the bottom. The total ascent/descent was 60cm. When the participant raised their leading foot to start the ascent, the stopwatch was started and stopped when the leading foot touched the bottom. The participants were given the following instruction ‘stand at the bottom of the stairs with your arms by your sides, when I say go, go up this side of the stairs [the stairs were being pointed out to the participant] and down the other. Go at your normal speed and if you would normally use the handrail, you may do so’. The test was repeated 3 times. The test was timed in seconds (s).
6.5.4.3 Leg extensor power analyser

The strength of the knee extensor muscles was determined using the Leg Extensor Power Analyser as shown in Figure 6.2. Leg extensor power was calculated using the supplied software which took into account a combination of force and velocity and has previously been described elsewhere (Bassey & Short, 1990). The participant was seated in the adjustable seat and asked to place their foot (on the leg to be tested) on the pedal of the analyser. They were then asked to push the pedal down as far as it would go. The seat was adjusted so that when the pedal was pushed down as far as it would go, the knee was fully extended. The seat was then locked in position, the pedal released and the flywheel brake briefly applied. Once the participant and the researcher was ready, the participant was given the instruction ‘when I say go, place your foot and the pedal and push down as hard and fast as you can’. Once the researcher had given the instruction to go, encouragement was given by saying ‘GO, GO, push as hard as you can’! This encouragement was given to all participants. One practice push was allowed. Three pushes were then taken. The push was recorded as watts (W) generated.
6.5.4.4 Self-paced walk test

For the self-paced walk test a standard stopwatch was used to measure the time taken to walk a 13m distance. A long uncarpeted corridor was used in order to avoid the need for a participant to make any turns. A clear start line was indicated and the participant instructed to place their toes on the line. The participant was then given the instruction ‘when I say go, walk at your normal pace until I tell you to stop’. Upon the word ‘go’, the stopwatch was started. Once the participant crossed the 13m walk line, the stopwatch was started. The finish line was not obvious to the participant to avoid them either consciously or subconsciously altering their speed as they neared the line. The test was repeated twice. The test was timed in seconds (s).
6.5.5 Passive Resistance to Motion

Passive resistance to motion was measured using the instrumentation described in chapter 5 (Figure 6.3). The subject was seated upright on the testing couch with the back supported and the hips flexed to 70°. The upper thighs were supported by the couch. The foot of the leg not being tested was placed on a box placed so that the knee was flexed to 90°. The axis of the testing system aligned with the femoral epicondyle of the leg to be tested. The height of the footplate was adjusted so that the ankle could be comfortably strapped to the crosspiece of the testing rig and that the knee would remain aligned with the axis of rotation of the rig throughout the movement.

Figure 6.3 Instrumentation for measurement of the resistance to motion.
Flexion/extension displacement at the knee was measured using a biaxial M180 electrogoniometer\textsuperscript{17}. Prior to attachment on the participant the electrogoniometer was zeroed using a universal goniometer (Figure 6.4). Two flexible plastic strips were attached to the ends of the electrogoniometer to facilitate fixation. The electrogoniometer was fixed over the knee joint with the ends aligned with the long axes of the thigh and shank (as identified by the bony landmarks).

![Electrogoniometer with universal goniometer](image)

**Figure 6.4** Electrogoniometer with universal goniometer used for calibration.

General muscle activity of the quadriceps muscle group was monitored using electromyography (EMG). The purpose of the EMG was to determine whether knee flexion/extension during the knee stiffness tests was passive. A Neurotrac \textsuperscript{18} programmed for EMG mode was used to measure the muscle activity (in $\mu$V) of the

\textsuperscript{17} Biometrics Ltd, Gwent, UK.

\textsuperscript{18} Verity Medical Ltd, Surrey
quadriceps muscle group. Self adhesive skin surface electrodes were placed over the muscle belly of quadriceps. The Neurotrac 2 manufacturers stated that a relaxed muscle should demonstrate less than 3.5 μV of activity and therefore the system was set to provide an alarm when readings from either muscle exceeded this value. The participant could see the readings on the unit and therefore the system acted as a biofeedback unit to help participants remain passive throughout the movement.

Participants were instructed to keep the leg as relaxed as possible during the testing. Each participant had their knee passively flexed and extended 5 times at both fast and slow velocities whilst the torque and displacement were simultaneously recorded. Data was sampled at a frequency of 50Hz.

6.6 Procedure

Before proceeding with the testing procedure, all participants were offered the opportunity to ask any further questions before giving their written consent to take part. The testing procedure that followed took the form of 1) brief interview, 2) clinical knee examination, 3) objective measures of function, 4) stiffness measures, 5) timed walk test. Figure 6.5 outlines the data collection procedure.
6.7 Data Processing

This section outlines the methods used to calculate WOMAC and SF -12 scores, walking speed and to normalise the LEP. The processing of the passive resistance to motion data in order to give stiffness values is also described.
6.7.1 Questionnaires

The WOMAC questionnaire utilised a Likert scale (1 – 5) where 1 represented no pain, no stiffness or no functional limitations. Although some studies have reported the WOMAC domains on a 0-100 scales (either by using a VAS scale for individual questions or by normalising the scores to a 0-100 scale), the original scoring system (Bellamy, 2000) scores pain from 0-20, stiffness from 0-8 and function 0-68. Individual answer were converted from the 1-5 scale to a 0-4 scale and summed according to the original scoring system. In addition, in order to facilitate comparison with other studies, scores were also normalised by using the following equations

\[
\text{nWOMAC}_{\text{pain}} = \left( \frac{\text{WOMAC pain}}{20} \right) \times 100
\]

\[
\text{nWOMAC}_{\text{stiffness}} = \left( \frac{\text{WOMAC stiffness}}{8} \right) \times 100
\]

\[
\text{nWOMAC}_{\text{function}} = \left( \frac{\text{WOMAC function}}{68} \right) \times 100
\]

Where the prefix ‘n’ stands for normalised.

SF-12 data was recoded and summed using the original scoring system designed by Ware, Kosinski, & Keller (1995). This system provided two scores – the Physical Component Summary (PCS) and the Mental Component Summary (MCS) – both of which are scored out of 100. This scoring system transformed the data to give a mean of 50 in the general population with a standard deviation of 10 (that is to say 95% of the general population will have a PCS and MCS of 30.4 to 69.2). Higher scores represented better physical functioning and mental health.
6.7.2 Objective measures of function

The TUG and stair ascent/descent tests were measured in seconds and needed no further processing. The LEP was measured in W and therefore to allow data to be compared between subjects, it required to be normalised. Previous studies (Frost, Lamb, & Robertson, 2002; Robertson et al., 1998) have used body mass (kg) and therefore LEP was normalised to body mass (NLEP) using the equation

\[ \text{NLEP} = \frac{\text{LEP}}{\text{body mass}}. \]

The time taken to complete the 13 m of the self paced walk test was converted to speed (m/s) by using the following equation;

\[ \text{walking speed} = \frac{13}{\text{time taken to complete walk test}} \]

6.7.3 Passive resistance to motion data

Following testing, torque and displacement data was processed as outlined in sections 4.4. and 5.4 to give the passive resistance to motion (PRM in Nm). A Matlab\textsuperscript{19} programme was then used to graph the passive resistance to motion against displacement during both flexion and extension.

From the flexion graph, stiffness in midrange and flexion was calculated from the slope on the line (Figure 6.6). The value of the torque and angle at which flexion stiffness was seen in increase greatly were also noted (Figure 6.6).

\textsuperscript{19} The Mathworks Inc. Natick, Massachusetts
Figure 6.6 Example of a passive resistance to motion vs displacement curve as the knee goes from extension to flexion (flexing).

From the extension graph, stiffness in midrange and extension were calculated from the slope of the line (Figure 6.7). The torque and angle values at which extension stiffness was observed to increase greatly were noted (Figure 6.7).

Figure 6.7 Example of a passive resistance to motion vs displacement curve as the knee goes from flexion to extension (extending).
Stiffness values were also normalised to thigh segment mass (Blackburn et al, 2004b) using the following equation example:

\[ \text{nfastextensionstiffness} = \frac{\text{fastextensionstiffness}}{0.1 \times \text{body mass}} \]

where thigh segment mass was represented by the equation 0.1 x body mass (Dempster, 1955).

All stiffness variables were similarly normalised. Threshold stiffness angles were normalised to range of motion. Flexion stiffness angles were normalised to maximum passive flexion. Extension stiffness angles were normalised to maximum range of motion (passive flexion – passive extension).

6.8 Statistical methods

Data was processed using Microsoft Excel and analysed using SPSS For Windows (v 16.0).

6.8.1 Power and sample size calculations

A sample size calculation (Lenth, 2009) based on previously published WOMAC stiffness data (Bachmeier et al, 2001) indicated that a sample size of 10 per group would provide a power of 0.7 to detect a difference of 2 points on the WOMAC stiffness scale (on a scale of 0-8) with a standard deviation of 1.7. The usefulness of these sample size calculations were however limited in predicting the sample size necessary to identify inter-group differences in the objective measures of stiffness. This study was therefore considered as an exploratory study, the results of which
could be used to provide post-hoc power and effect size calculations in order to inform future work.

6.8.1.1 Calculation of effect sizes

Where statistically significant results were found, effect sizes were reported. Where t-tests were used to determine between groups differences, Cohens d was calculated (Cohen, 1992). Where ANOVA was used to determine between group differences, omega squared ($\omega^2$) was used as a measure of effect size (Kinnear & Gray, 2009; Levine & Hullett, 2002). As $\omega^2$ is not given in the SPSS reports for the ANOVA, it was calculated by hand using the data provided by the ANOVA procedure.

$$\omega^2 = \frac{SS_{main effect} - (df_{main effect})(MS_{error})}{SS_{total} + MS_{error}}$$ (Vincent, 2005)

Kinnear and Gray (2009) suggested a range of values that could be used to assess values of $\omega^2$ (Table 6.3).

<table>
<thead>
<tr>
<th>Size of effect</th>
<th>Effect size ($\omega^2$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Small</td>
<td>$0.01 \leq \omega^2 &lt; 0.06$</td>
</tr>
<tr>
<td>Medium</td>
<td>$0.06 \leq \omega^2 &lt; 0.14$</td>
</tr>
<tr>
<td>Large</td>
<td>$\omega^2 \geq 0.14$</td>
</tr>
</tbody>
</table>

Effect sizes for the correlation coefficients were indicated by $r^2$ (coefficient of determination) and $\rho^2$. Kinnear and Gray (2009) suggested a range of values that could be used to assess the effect size of the correlation coefficients (Table 6.4).
Table 6.4 Effect sizes for correlation coefficients

<table>
<thead>
<tr>
<th>Size of effect</th>
<th>Effect size ( r^2 ) or ( \rho^2 )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Small</td>
<td>&lt; 0.01 (&lt;1%)</td>
</tr>
<tr>
<td>Medium</td>
<td>0.01 to 0.10 (1-10%)</td>
</tr>
<tr>
<td>Large</td>
<td>&gt; 0.10 (&gt;10%)</td>
</tr>
</tbody>
</table>

6.8.1.2 Post-hoc sample size calculations

Using effect sizes calculated as above, post-hoc sample size calculations were undertaken in order to inform future work. These calculations were undertaken using an on-line calculator provided by Russ Lenth (Lenth, 2009) using standard deviations, expected mean differences and a power of 0.8.

6.8.2 Descriptive statistics

As an exploratory study, descriptive statistics were considered particularly useful in generating data that could be used to inform future sample size and power calculations. Interval/ratio data were evaluated for normality of distribution using the Shapiro-Wilks test (n < 50) or the Kolmogorov-Smirnov test (n > 50). Results of the normality tests are provided in Appendix 4. Normally distributed populations were described using mean and standard deviation. Where data were presented graphically, bar charts were used with errors bars to indicate the standard deviations. Non-normally distributed data were described using medians and inter-quartile ranges (IQR). Where data was presented graphically, boxplots indicating the median, IQR and max/min were used.
6.8.3 Inferential statistics

6.8.3.1 Differences

Differences between groups (control, OA and TKA) were determined using one-way ANOVA where the assumptions for an ANOVA could be met (Munro BH, 2001).

Where a potential confounding variable was identified, its effect was determined using factorial ANOVA to examine the interaction between the confounding variable and the dependent variable (Kinnear & Gray, 2009).

Where the ANOVA showed significant differences, post-hoc analysis using the Tukey test was requested from the procedure. The Tukey test was chosen over other possible tests as it is more powerful than the Bonferroni and the Scheffé (Kinnear & Gray, 2009), particularly if only pairwise comparisons are to be undertaken.

Where data was not normally distributed, between group differences were explored using the Kruskall-Wallis test with post-hoc independent t-tests where appropriate. In order to reduce the potential for making Type I errors, the alpha level for the post-hoc tests was adjusted using the Bonferroni correction.
6.8.3.2 Relationships

Relationships were evaluated using correlation. Where data was normally distributed, Pearson's Product Moment Correlation Coefficient was used. Where data could not be shown to be normally distributed, Spearman's Correlation Coefficient was used. The strength of the association was determined according to Munro BH (2001) (Table 6.5).

<table>
<thead>
<tr>
<th>Correlation coefficient</th>
<th>Strength of association</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.00 – 0.25</td>
<td>little if any</td>
</tr>
<tr>
<td>0.26 – 0.49</td>
<td>low</td>
</tr>
<tr>
<td>0.50 – 0.69</td>
<td>moderate</td>
</tr>
<tr>
<td>0.70 – 0.89</td>
<td>high</td>
</tr>
<tr>
<td>0.90 – 1.00</td>
<td>very high</td>
</tr>
</tbody>
</table>
7 Clinical results

This results chapter describes the results of the clinical phase of the study. Recruitment, participant demographics, descriptive statistics and inferential tests relating to the study aims outlined in chapter 3 are detailed.

7.1 Participants

In part 1 of the study, 24 patients scheduled to undergo primary TKA for OA were sent letters prior to their appointment at the pre-admission clinic. Eight patients (33%) agreed to participate. Forty-six patients who had undergone primary TKA for OA within the preceding 10-14 months were also invited to take part by letter. Fifteen patients (33%) agreed to participate. Twelve volunteers from local community groups agreed to act as the control group. Participant characteristics are outlined in Table 7.1. All variables were normally distributed (Appendix 4) and are therefore presented as mean (SD). Of the 15 participants in the TKA group, 8 had received a Kinemax²⁰ prosthesis and 7 received a Triathlon. No participant in the TKA group experienced any significant complications (such as infection, DVT, loosening or manipulation under anaesthesia) resulting in an increased length of stay.

---

²⁰ Stryker, UK
Table 7.1 Participant characteristics – part 1

<table>
<thead>
<tr>
<th></th>
<th>OA (n = 8)</th>
<th>TKA (n = 15)</th>
<th>Control (n = 12)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>73.88 (5.25)</td>
<td>70.80 (7.75)</td>
<td>68.92 (8.30)</td>
</tr>
<tr>
<td>Males (n)</td>
<td>5 (63%)</td>
<td>11 (73%)</td>
<td>3 (25%)</td>
</tr>
<tr>
<td>Females (n)</td>
<td>3 (37%)</td>
<td>4 (27%)</td>
<td>9 (75%)</td>
</tr>
<tr>
<td>Height (m)</td>
<td>1.66 (0.11)</td>
<td>1.67 (0.10)</td>
<td>1.66 (0.09)</td>
</tr>
<tr>
<td>Mass (kg)</td>
<td>79.15 (21.34)</td>
<td>84.07 (14.55)</td>
<td>78.17 (19.43)</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>28.28 (4.91)</td>
<td>30.04 (4.77)</td>
<td>28.30 (7.27)</td>
</tr>
</tbody>
</table>

All data met the assumption of homogeneity of variance (Appendix 5) and therefore a one-way ANOVA was used to detect differences between groups. No significant differences in age ($F(2,32) = 1.055, p = 0.360$), height ($F (2,32) = 0.059, p = 0.943$), weight ($F (2,32) = 0.411, p = 0.667$) or BMI ($F(2,32) = 0.394, p = 0.677$) were found. The male:female ratio was significantly different between the groups ($\chi^2 (2, N = 35) = 6.558, p = 0.038$). As significant differences have been found between gender in young, healthy subjects, gender was checked for its potential as a confounding variable in each analysis (Appendix 6). Overall the analysis of the participant characteristics suggested that the groups were broadly similar other than in gender proportions.

Table 7.2 outlines the anthropometric characteristics of the lower limb of all participants in part 1. Data were calculated from height and weight using previously documented equations (section 4.5.1). All data were ratio level and normally distributed (Appendix 4) and are therefore presented as mean (SD).
Table 7.2 Anthropometric data

<table>
<thead>
<tr>
<th></th>
<th>OA ( n = 8 )</th>
<th>TKA ( n = 15 )</th>
<th>Control ( n = 12 )</th>
<th>F-ratio</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length of shank and foot (m)</td>
<td>0.474 (0.030)</td>
<td>0.477 (0.028)</td>
<td>0.474 (0.025)</td>
<td>0.057</td>
<td>0.945</td>
</tr>
<tr>
<td>Mass of shank and foot (kg)</td>
<td>4.591 (1.237)</td>
<td>4.876 (0.844)</td>
<td>4.534 (1.127)</td>
<td>0.411</td>
<td>0.667</td>
</tr>
<tr>
<td>Position of centre of mass of shank and foot (distance from proximal joint) (m)</td>
<td>0.225 (0.014)</td>
<td>0.227 (0.013)</td>
<td>0.225 (0.012)</td>
<td>0.054</td>
<td>0.947</td>
</tr>
<tr>
<td>Radius of gyration (distance from proximal joint) (m)</td>
<td>0.348 (0.022)</td>
<td>0.351 (0.020)</td>
<td>0.349 (0.018)</td>
<td>0.052</td>
<td>0.949</td>
</tr>
<tr>
<td>Thigh circumference (m)</td>
<td>0.463 (0.073)</td>
<td>0.485 (0.059)</td>
<td>0.485 (0.075)</td>
<td>0.322</td>
<td>0.727</td>
</tr>
<tr>
<td>Thigh segment mass (kg)</td>
<td>7.915 (2.134)</td>
<td>8.407 (1.455)</td>
<td>7.817 (1.943)</td>
<td>0.411</td>
<td>0.667</td>
</tr>
</tbody>
</table>

A one-way ANOVA (df = 2,32) showed that there were no significant differences (p > 0.05) between groups in any of the anthropometric variables calculated from height and weight or thigh circumference.

As thigh mass was used as a normalisation variable for stiffness, it was tested for gender differences. A t-test found no significant difference in thigh mass between genders (Appendix 6).

In part 2 of the study, 160 stiffness questionnaires were posted to potential participants in the TKA group. Sixty-one (38%) questionnaires were returned. A further 32 patients awaiting TKA who were approached in pre-admission clinic agreed to participate and completed questionnaires. Table 7.3 outlines the participant characteristics from part 2.
Table 7.3 Participant characteristics – part 2

<table>
<thead>
<tr>
<th></th>
<th>OA N = 32</th>
<th>TKA N = 61</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years ± sd)</td>
<td>68.1 (10.1)</td>
<td>71.4 (9.8)</td>
</tr>
<tr>
<td>Males (%)</td>
<td>56</td>
<td>38</td>
</tr>
<tr>
<td>Females (%)</td>
<td>44</td>
<td>62</td>
</tr>
</tbody>
</table>

Although there appeared to be a difference in the proportion of males:females within this group, these differences not found to be significant ($\chi^2 = 3.148, p = 0.076$). Age was not normally distributed (Kolomogorov-Smirnov test statistic = 0.133, $p = 0.001$) and therefore the Mann-Whitney U-test was used to determine differences. No significant difference in age between the two groups ($U = 498.00, p = 0.130$) was found.

7.2 Clinical examination

Range of motion and Knee Society Score (KSS) were recorded at the affected knee (Table 7.4). Full extension of the knee was represented by a value of 0°. A positive value for passive extension indicated a fixed flexion contracture. An extensor lag was recorded if the participant was unable to maintain the knee at its fullest extension when the leg was raised off the examination couch. A value of 0° indicated that the participant was able to maintain the full range of passive extension when the leg was raised off the examination couch.

A higher KSS indicated less pain, greater movement, better stability and alignment. All variables (passive extension, passive flexion, extensor lag, active flexion, range and KSS) were not normally distributed (Appendix 4) and therefore data are presented as median and IQR.
Table 7.4 Knee range of motion

<table>
<thead>
<tr>
<th>Knee range of motion</th>
<th>OA N = 8</th>
<th>TKA N = 15</th>
<th>Control N = 12</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Passive</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Extension (degrees)*</td>
<td>5.50 (6.75)</td>
<td>2.00 (6.00)</td>
<td>0.00 (1.50)</td>
</tr>
<tr>
<td>Flexion (degrees)*</td>
<td>110.00 (13.75)</td>
<td>115.00 (13.00)</td>
<td>128.50 (27.25)</td>
</tr>
<tr>
<td><strong>Active</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Extensor lag (degrees)</td>
<td>0.00 (1.50)</td>
<td>0.00 (0.00)</td>
<td>0.00 (0.00)</td>
</tr>
<tr>
<td>Flexion (degrees)*</td>
<td>110.00 (13.75)</td>
<td>110.00 (15.00)</td>
<td>120.00 (17.00)</td>
</tr>
<tr>
<td><strong>Range of motion</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(degrees)</td>
<td>106.50 (18.75)</td>
<td>115.00 (16.00)</td>
<td>131.50 (25.25)</td>
</tr>
</tbody>
</table>

* significant differences between groups.

There were no differences in any variable between gender (Appendix 6) and therefore gender was not considered to be a potential covariate. As data was not normally distributed, the non-parametric Kruskall-Wallis test was used to determine differences between groups. Significant differences were found between the three groups in all variables with the exception of extensor lag: passive extension ($\chi^2=10.371$, df = 2, $p = 0.006$), passive flexion ($\chi^2=10.249$, df = 2, $p = 0.006$), extensor lag ($\chi^2=1.738$, df = 2, $p = 0.419$), active flexion ($\chi^2=9.171$, df = 2, $p = 0.010$), range of motion ($\chi^2=13.292$, df = 2, $p = 0.001$). Post-hoc Mann-Whitney U-tests (Table 7.5) with a Bonferroni correction applied to the alpha level, were subsequently performed in order to determine where differences lay.
Table 7.5 Results of the post-hoc Mann-Whitney U-tests for ROM variables

<table>
<thead>
<tr>
<th></th>
<th>Passive extension</th>
<th>Passive flexion</th>
<th>Active flexion</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control vs OA</td>
<td>0.002*</td>
<td>0.010*</td>
<td>0.115</td>
<td>0.002*</td>
</tr>
<tr>
<td>Control vs TKA</td>
<td>0.075</td>
<td>0.003*</td>
<td>0.002*</td>
<td>0.001*</td>
</tr>
<tr>
<td>OA vs TKA</td>
<td>0.115</td>
<td>0.825</td>
<td>0.428</td>
<td>0.591</td>
</tr>
</tbody>
</table>

* = significant following a Bonferroni correction

The Bonferroni correction divided the original alpha level (0.05) by the number of pairwise comparisons. Thus the level of significance for the post-hoc tests was set at 0.05/3 = 0.017. The control group had significantly greater passive extension and greater passive flexion (and thus also significantly greater range) than the OA group. Active and passive flexion (and also range) was also significantly greater in the control group than the TKA group. Passive extension was not significantly different between the TKA and the control group. No significant differences were found between the OA and TKA groups in any of the range of motion variables.

The Knee Society Score (possible range 0-100, worst-best) was completed for all participants (n = 35). Data was not normally distributed and therefore data are presented as median and IQR. The control group (n = 12) had a median score of 97.00 and the TKA group (n = 15) a median score of 88.00 which are very close the ceiling of 100 (Figure 7.1). The OA group had the lowest score (median = 63.5).
The Kruskall-Wallis test found significant differences in the Knee Society Score ($\chi^2 = 14.516$, df = 2, $p = 0.001$) between groups. Unsurprisingly, post-hoc analysis (Mann-Whitney U–tests with a Bonferroni correction) confirmed that the OA group (n = 8) had significantly lower scores (median 63.50) than either the control group ($p < 0.001$) or the TKA group ($p = 0.001$). There were no differences between the control group and the TKA group ($p = 0.053$).

7.3 WOMAC and SF-12

WOMAC and SF-12 scores are briefly presented here. Summary statistics and further analysis is presented in Appendices 7 and 8.
7.3.1 WOMAC

As expected, the OA group demonstrated significantly worse pain and functional limitations that either the TKA (p < 0.001) or control (p < 0.001) group (Appendix 7). There were however no significant differences between TKA and control in pain (p = 0.028) or function (p = 0.548) scores (Appendix 7).

The WOMAC stiffness scores were dichotomised into those who reported no stiffness (stiffness score = 0) or stiffness (stiffness score > 0). Sixty-seven percent of the control group (n = 8) and 60% of the TKA group (n = 9) reported no stiffness compared to only 25% of the OA group (n = 2). There was no significant difference in the proportion of participants reporting any stiffness using the WOMAC scale (Fishers Exact test = 3.533, p = 0.196).

Figure 7.2 showed that the OA had worse self-reported stiffness using the WOMAC score, than either the TKA or control groups although the Kruskall-Wallis test showed no significant differences between groups ($\chi^2 = 5.905$, df = 2, p = 0.052).
However, as Figure 7.2 indicated, there was one significant outlier in the control group. As the Kruskall-Wallis test showed a p-value which lay just outside the level set for significance, the data was reanalysed with this outlier removed to determine the effect of this outlier on the overall significance of the differences. With the outlier removed, the Kruskall-Wallis test showed significant differences between the groups in WOMAC stiffness ($\chi^2 = 7.780$, df = 2, $p = 0.020$). Post-hoc analysis (Table 7.6) indicated that that control group had significantly lower stiffness than the OA group but no other significant between group differences were observed.
Table 7.6 Results of Mann-Whitney U-tests for WOMAC stiffness

<table>
<thead>
<tr>
<th>Pairs</th>
<th>WOMAC Stiffness</th>
<th>p =</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control vs OA</td>
<td>0.016*</td>
<td></td>
</tr>
<tr>
<td>Control vs TKA</td>
<td>0.357</td>
<td></td>
</tr>
<tr>
<td>OA vs TKA</td>
<td>0.056</td>
<td></td>
</tr>
</tbody>
</table>

* = significant with a Bonferroni correction

7.3.2 SF-12

Scores from the SF-12 were normally distributed and therefore differences between groups were analysed using a one-way ANOVA (Appendix 8). Post-hoc analysis was undertaken using Tukey tests. The results from the post-hoc analysis showed that the OA group also reported worse PCS scores (Appendix 8) than either the TKA (p = 0.028) or the control group (p = 0.017). MCS scores were not significantly different between groups (p = 0.110).

7.4 Visual Analogue Score for stiffness

VAS stiffness data was available from 128 participants (data was missing for one participant). The data was scored from 0-100 where 100 represented maximum stiffness. Data was not normally distributed and is therefore presented as median and IQR. There were no significant differences between genders (Appendix 6) and therefore gender was not considered as a co-variate. The OA group (n = 40) reported the highest VAS stiffness scores (median = 60.00), the TKA group (n = 76) the second highest (median = 20.00) and the control group (n = 12) the lowest (median = 4.50). The median and inter-quartile range can be seen in Figure 7.3. VAS stiffness
scores for both the OA group and TKA group demonstrated considerable variance as indicated by large inter-quartile ranges (OA = 47.75, TKA = 32.00)

![Figure 7.3 VAS stiffness scores by group](image)

Scores were dichotomised into no stiffness (VAS score = 0) or stiffness present (VAS score > 0). Forty-two percent (n = 5) of the control group and 19% (n = 15) of the TKA group recorded scores of 0 (no stiffness) compared to 0% of OA group. A Fishers Exact test (conducted as 2 cells had an expected frequency of less than 5) of association showed that there was a significant association between presence of stiffness and group (Fishers Exact test = 16.398, p < 0.001). The Kruskall-Wallis test was undertaken on the actual VAS scores and this test also showed that the differences in VAS stiffness between groups were significant ($\chi^2 = 33.244$, df = 2, p
< 0.001). Post-hoc Mann-Whitney U-tests (with a Bonferroni correction) showed that the control group had significantly less stiffness than the OA group (p < 0.001). The TKA group also had significantly less stiffness than the OA group (p < 0.001). Differences between the control group and TKA group (p = 0.032) were not found to be significant once the Bonferroni correction had been applied. The control group demonstrated one outlier (indicated by a * in Figure 7.3) and therefore the analysis was also undertaken with this outlier removed. The Kruskall-Wallis test showed significant differences between groups ($\chi^2 = 37.180$, df = 2, p < 0.001). Post-hoc Mann-Whitney U-tests (with a Bonferroni correction) showed that the control group and TKA group had significantly less stiffness than the OA group (p < 0.001). The differences between the TKA and the control group were also significant (p = 0.006).

7.5 Self-reported descriptors of stiffness

Of 128 participants, 20 (16%) recorded a score of 0 (no stiffness). Of these 20, 5 were in the control group and 15 in the TKA group. All participants in the OA group reported some level of stiffness. Those who recorded a score of > 0 (n = 108) were asked to choose from a list of words (Appendix 3), any that described their stiffness. There was no limit to the number of words a participant could choose. There was a significant difference in the median number of words used (Table 7.7) between groups (Kruskall-Wallis test, $\chi^2 = 29.327$, df = 2, p < 0.001). Post-hoc analysis showed that differences existed between the OA and TKA group (p < 0.001) and the OA and control group (p = 0.001). There were no significant differences between the TKA and control groups (p = 0.272).
Table 7.7 Total number of words used to describe stiffness

<table>
<thead>
<tr>
<th></th>
<th>OA</th>
<th>TKA</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median</td>
<td>4.0</td>
<td>1.0</td>
<td>0.0</td>
</tr>
<tr>
<td>IQR</td>
<td>5.75</td>
<td>3.0</td>
<td>3.0</td>
</tr>
</tbody>
</table>

There was a significant positive correlation (Spearmans \( \rho = 0.850 \), \( p < 0.001 \), \( \rho^2 = 0.722 \)) between the total number of words used to describe stiffness and the severity of self-perceived stiffness (Figure 7.4). Those with higher self-reported stiffness used a greater number of words to describe their stiffness.

Figure 7.4 Scatterplot of self-perceived stiffness score and total number of words used to describe stiffness
Words were then categorised into pain related, difficulty with movement and sensations. These categories were based on previous work (Rhind, 1987). The frequency that words were chosen is described in Table 7.8. Overall, of the 21 words available, 19 words were circled by 97 participants (11 participants who indicated some severity of stiffness selected no words from the list). The total number of words used was 368. Words relating to difficulty with movement were selected most frequently (52%) however over a third of the words used (35%) were pain related. Unsurprisingly, the most commonly used word was ‘stiff’ although this was only selected by 43% of participants who reported stiffness. After stiff, the most frequently used word was ‘aches’. Of those who reported a sensation of stiffness, 28% of the TKA group, 55% of the OA group and 43% of the control group used this word.

Table 7.8 Frequency of words used to describe stiffness

<table>
<thead>
<tr>
<th>Pain related words</th>
<th>N =</th>
<th>Difficulty with movement</th>
<th>N =</th>
<th>Sensations</th>
<th>N =</th>
</tr>
</thead>
<tbody>
<tr>
<td>Painful</td>
<td>30</td>
<td>Limited movement</td>
<td>34</td>
<td>Creaking</td>
<td>22</td>
</tr>
<tr>
<td>Aches</td>
<td>42</td>
<td>Stiff</td>
<td>46</td>
<td>Grinding</td>
<td>17</td>
</tr>
<tr>
<td>Hurts</td>
<td>24</td>
<td>Rigid</td>
<td>2</td>
<td>Grating</td>
<td>10</td>
</tr>
<tr>
<td>Sore</td>
<td>32</td>
<td>Stubborn</td>
<td>5</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Stuck</td>
<td>5</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Set</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Inflexible</td>
<td>10</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Fixed</td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Locked</td>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Immobile</td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Solid</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Restricted</td>
<td>35</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Tight</td>
<td>37</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Tense</td>
<td>9</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>128</td>
<td></td>
<td>191</td>
<td></td>
<td>49</td>
</tr>
<tr>
<td>% of overall total</td>
<td>35</td>
<td></td>
<td>52</td>
<td></td>
<td>13</td>
</tr>
</tbody>
</table>
Of those who reported any stiffness, Figure 7.5 shows that a significantly larger proportion of the OA group included words from the pain category to describe their stiffness (Fishers Exact test = 12.670, p = 0.001).

![Figure 7.5. Percentage of participants who used words from the pain category to describe stiffness.](image)

Although Figure 7.6 shows that the control group were less likely to use words from the ‘difficulty with movement’ to describe their stiffness, the difference in the proportion of participants within each group was not significant (Fishers Exact test = 2.183, p = 0.336).
Figure 7.6 Percentage of participants who used words from the ‘difficulty with movement’ category to describe stiffness.

Interestingly, only 7% of the TKA group used words relating to sensation to describe their stiffness, compared to 43% of controls and 80% of the OA group (Figure 7.7). These differences were significant (Fishers Exact test = 35.812, p < 0.001).
The combinations of word type were also explored by group (Table 7.9). Of the 108 participants who reported stiffness, 97 circled words to describe their stiffness. Of the 97 who described their stiffness, 39 (40%) used words from a single category, 39 (40%) used two categories and 19 (20%) used words from all three categories. The majority (82%) of participants in the OA group who had a stiffness score > 0 and described their stiffness (n = 38), used words which included those from the pain category. In comparison, only 48% of those in the TKA group and 43% from the
control group who reported stiffness included words from the pain category in their descriptions of stiffness.

Table 7.9 Combinations of words used to describe stiffness

<table>
<thead>
<tr>
<th></th>
<th>OA N = 40</th>
<th>TKA N = 61</th>
<th>Control N = 7</th>
<th>Total N = 108</th>
</tr>
</thead>
<tbody>
<tr>
<td>No descriptors</td>
<td>5.0%</td>
<td>11.5%</td>
<td>28.6%</td>
<td>10.2%</td>
</tr>
<tr>
<td>Pain only</td>
<td>12.5%</td>
<td>6.6%</td>
<td>8.3%</td>
<td></td>
</tr>
<tr>
<td>Difficulty with mvt only</td>
<td>7.5%</td>
<td>41.0%</td>
<td>28.6%</td>
<td>27.7%</td>
</tr>
<tr>
<td>Sensation only</td>
<td>0%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain + difficulty with mvt</td>
<td>15.0%</td>
<td>34.4%</td>
<td>25.0%</td>
<td></td>
</tr>
<tr>
<td>Pain + sensation</td>
<td>7.5%</td>
<td>1.6%</td>
<td>14.3%</td>
<td>4.6%</td>
</tr>
<tr>
<td>Difficult with mvt + sensation</td>
<td>10.0%</td>
<td>4.9%</td>
<td>6.5%</td>
<td></td>
</tr>
<tr>
<td>Pain + difficulty with mvt + sensation</td>
<td>42.5%</td>
<td>28.6%</td>
<td>17.6%</td>
<td></td>
</tr>
</tbody>
</table>

7.6 Performance based measures of function

The TUG and the stair ascent/descent test were not normally distributed (Appendix 4) and are therefore presented as median (IQR) (Table 7.10). Walking speed and normalised leg extensor power were however, normally distributed (Appendix 4), and are therefore presented as mean (sd). One subject in each of the OA and the control group did not complete the leg extensor power test due to technical problems with the computer which controlled the data capture for the leg extensor power analyser on the day of testing.
Table 7.10 Summary statistics for the objective measures of function

<table>
<thead>
<tr>
<th></th>
<th>OA N = 8</th>
<th>TKA N = 15</th>
<th>Control N = 12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Timed Up and Go (s)</td>
<td>11.72 (5.62)</td>
<td>9.06 (2.31)</td>
<td>8.50 (1.49)</td>
</tr>
<tr>
<td>Stair ascent test (s)</td>
<td>6.55 (7.66)</td>
<td>4.85 (1.58)</td>
<td>4.75 (1.81)</td>
</tr>
<tr>
<td>*Walking speed (m/s)</td>
<td>1.070 (0.308)</td>
<td>1.352 (0.239)</td>
<td>1.299 (0.249)</td>
</tr>
<tr>
<td>*Normalised LEP(W/kg)</td>
<td>0.557 (0.273)</td>
<td>0.763 (0.278)</td>
<td>0.612 (0.457)</td>
</tr>
</tbody>
</table>

The Kruskall-Wallis test showed significant differences between groups for the TUG ($\chi^2 = 11.010$, df = 2, $p = 0.004$) and the stair ascent test ($\chi^2 = 7.148$, df = 2, $p = 0.028$). Results of the post-hoc Mann-Whitney U-tests are shown at the end of the section (Table 7.12)

There were significant differences between gender in walking speed and normalised leg extensor power (Appendix 6). Figure 7.8 however indicated that differences between groups were not dependent on gender.
Figure 7.8 Normalised leg extensor power by group and gender

Levene’s test showed that the normalised leg extensor power met the assumption of homogeneity of variance (Appendix 5) and therefore, along with a normal distribution, met the assumptions required for the ANOVA. A two-factor between subjects ANOVA (using both group and gender as independent variables) confirmed that differences in leg extensor power between gender existed ($F(1,32) = 14.392, p = 0.001, \omega^2 = 0.289$) but that no significant interaction was present between group and gender ($F(2,32) = 0.656, p = 0.527$). There were no differences in leg extensor power between groups ($F(2,32) = 1.909, p = 0.168, \omega^2 = 0.004$). As no difference between groups was detected and normalised leg extensor power demonstrated a normal distribution, 95% CI’s for pair of groups were constructed (Table 7.11).
Table 7.11 95% confidence intervals of the difference in normalised leg extensor power between groups

<table>
<thead>
<tr>
<th>Group pairs</th>
<th>95% CI of the difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control – OA</td>
<td>-0.353, 0.464</td>
</tr>
<tr>
<td>Control – TKA</td>
<td>-0.449, 0.147</td>
</tr>
<tr>
<td>OA - TKA</td>
<td>-0.470, 0.058</td>
</tr>
</tbody>
</table>

The 95% CI of the differences shows that 0 lies between the upper and lower bounds for all variables, confirming that there was no significant difference between groups.

A graph of walking speed by group and gender (Figure 7.9) shows that differences between groups were not dependent on gender.

![Figure 7.9 Walking speed by group and gender.](image-url)
Levene’s test showed that walking speed met the assumption of homogeneity of variance (Appendix 5) and thus met the assumptions of the ANOVA. A factorial ANOVA confirmed that that differences in walking speed between genders exist (F(1,34) = 10.541, p = 0.003, $\omega^2 = 0.194$) and that no significant interaction was present (F(2,34) = 0.900, p = 0.418) confirming that differences between groups were not dependent on gender. Once differences in gender were taken into account, differences in walking speed between the 3 groups also exist (F(2,34) = 5.324, p = 0.011, $\omega^2 = 0.176$). Post-hoc tests (Table 7.12) were undertaken (Mann-Whitney U tests for the TUG, Tukeys’ tests for walking speed, to determine where differences lay.

Table 7.12 p-values for post-hoc analysis of performance based measures of function

<table>
<thead>
<tr>
<th>Pairs</th>
<th>TUG</th>
<th>Stair ascent/descent</th>
<th>Walking speed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control vs OA</td>
<td>0.004*</td>
<td>0.020</td>
<td>0.146</td>
</tr>
<tr>
<td>Control vs TKA</td>
<td>0.614</td>
<td>0.905</td>
<td>0.856</td>
</tr>
<tr>
<td>OA vs TKA</td>
<td>0.001*</td>
<td>0.013*</td>
<td>0.047†</td>
</tr>
</tbody>
</table>

* = significant results once Bonferroni correction applied,
† = significant Tukeys test

The post-hoc tests showed that the OA group was significantly slower at the TUG than either the TKA group or the control group. The OA group was also significantly slower at the stair/ascent test and walking than the TKA group. There were no significant differences between the TKA and control group in any variable.
7.7 Objective measures of stiffness

Stiffness was calculated as the slope of the line relating passive resistance to motion and angular displacement. Three phases were identified, the flexion phase, the mid-range phase and the extension phase. Stiffness was calculated in the following: in the flexion phase as the knee was flexed (flexion stiffness), extension phase as the knee was extended (extension stiffness) and midrange. Data was calculated for movement at both slow and fast velocity.

As three trials for each participant were recorded, reliability coefficients of the stiffness coefficients and stiffness threshold angles and torques were calculated. Table 7.13 presents the ICC (model 3,1) and the 95% confidence intervals of the ICC.

Table 7.13 ICC (95% CI) values for stiffness variables

<table>
<thead>
<tr>
<th>Phase</th>
<th>Stiffness</th>
<th>Threshold stiffness angle</th>
<th>Threshold stiffness torque</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fast extension</td>
<td>0.379</td>
<td>(0.147 – 0.610)</td>
<td>(0.690 – 0.903)</td>
</tr>
<tr>
<td>Fast flexion</td>
<td>0.660</td>
<td>(0.474 – 0.807)</td>
<td>(0.800 – 0.940)</td>
</tr>
<tr>
<td>Slow extension</td>
<td>0.551</td>
<td>(0.340 – 0.734)</td>
<td>(0.714 – 0.910)</td>
</tr>
<tr>
<td>Slow flexion</td>
<td>0.639</td>
<td>(0.451 – 0.791)</td>
<td>(0.918 – 0.976)</td>
</tr>
</tbody>
</table>

Table 7.13 shows that the reliability of stiffness coefficients could be considered as fair to moderate (0.4 – 0.75) (Shrout & Fleiss, 1979) with the exception of fast extension stiffness. All other variables showed excellent reliability (> 0.75).
One participant was unable to relax sufficiently in order to allow the movement to be passive.

### 7.7.1 Raw stiffness values

Data was not normally distributed (Appendix 4) (with the exception of flexion stiffness and midrange stiffness at the fast velocity) and are therefore presented as medians (IQR). No differences in gender were identified (Appendix 6) and therefore gender was not included as a potential covariate.

Fast extension stiffness, slow extension stiffness and slow flexion stiffness were not normally distributed so the Kruskal-Wallis tests were used to determine differences between groups. Fast flexion stiffness was normally distributed and showed homogeneity of variance (Appendix 5) and therefore between groups differences were determined using the one-way ANOVA.

Although Figure 7.10 shows that the TKA group had higher median stiffness in extension at the fast velocity (control = 0.610, OA = 0.638, TKA = 0.998), it also shows that the TKA had a larger variance. The Kruskal-Wallis test confirmed that differences in fast extension stiffness between the groups were not significant ($\chi^2 = 1.089$, df = 2, p = 0.580).
As fast flexion stiffness was normally distributed, data were presented as mean (sd).

Figure 7.11 showed that all variables demonstrated considerable variance.
A one-way ANOVA showed no significant differences between groups in fast flexion stiffness ($F(2,28) = 0.199, p = 0.821, \omega^2 = -0.058$).

The midrange stiffness during flexion and extension was averaged for each participant. As midrange stiffness at the fast velocity was normally distributed, data were presented as mean (sd) (Figure 7.12). Figure 7.12 indicated that the OA group had the smallest amount of midrange stiffness; the TKA and control groups had very similar values.
A one-way ANOVA indicated that differences between groups were not significant ($F(2, 25) = 0.451, p = 0.642, \omega^2 = -0.039$).

At the slow velocity, variances for stiffness were smaller (Figure 7.13 to Figure 7.15). The control group had a smaller median value for slow extension stiffness (Figure 7.13) (control = 0.343, OA = 0.606, TKA = 0.614) but the Kruskall-Wallis test showed that these differences were not significant ($\chi^2 = 3.100, df = 2, p = 0.212$).
Figure 7.13 Slow extension stiffness by group

The TKA group also had higher median values for slow flexion stiffness (control = 0.487, OA = 0.360, TKA = 0.537) (Figure 7.14) but these differences were not significantly different ($\chi^2 = 3.250, df = 2, p = 0.197$).
Figure 7.14 Slow flexion stiffness by group

The OA showed smaller values for slow midrange stiffness (Figure 7.15) but the Kruskall-Wallis test showed that these differences were not significant ($\chi^2 = 0.657$, df = 2, p = 0.720).
Figure 7.15 Average slow mid-range stiffness by group

Stiffness values at fast and slow velocities were also compared to determine whether speed of rotation resulted in a change in stiffness. As data were not normally distributed, the Wilcoxon-signed Ranks test was used to compare fast and slow extension and flexion stiffness within subjects.

Fast extension stiffness showed greater variability than the slow extension stiffness (Figure 7.16) but even taking this into account, there were significant differences in extension stiffness between the two velocities (Z (28) = -2.300, p = 0.021).
Fast flexion stiffness showed greater variability (Figure 7.17) than slow flexion stiffness. There were no significant differences between velocities for flexion stiffness ($Z(29) = -1.222, p = 0.222$).
7.7.2 Normalised stiffness values

Stiffness values were normalised to thigh mass (Nm/degree/kg). Normalised extension stiffness (both fast and slow) were normally distributed (Appendix 4) and were presented as mean (sd). The assumption of homogeneity of variance was met (Appendix 5) and therefore a one-way ANOVA was used to determine whether there were differences between groups. Normalised flexion stiffness (both fast and slow) was not normally distributed (Appendix 4) and were presented as median (IQR). The Kruskal-Wallis test was used to determine whether differences between groups were
present. No differences between gender were found (Appendix 6) and therefore gender was not considered as a confounding variable.

Figure 7.18 shows that the TKA had the highest values for normalised fast extension stiffness but also shows the large variance in both the control and TKA groups. A one-way ANOVA showed no significant differences between group in normalised fast extension stiffness ($F(2,25) = 0.307, p = 0.738, \omega^2 = -0.052$).

![Figure 7.18 Normalised fast extension stiffness by group](image)

Figure 7.18 Normalised fast extension stiffness by group

Figure 7.19 shows that the TKA group also had the highest normalised fast flexion stiffness but again high variances were seen in all groups. The Kruskall-Wallis test showed no significant differences ($\chi^2 = 0.837, df = 2, p = 0.658$) between groups in normalised fast flexion stiffness.

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195
At the slow velocity, variances were smaller (Figure 7.20 and Figure 7.21). The TKA group continued to show higher stiffness values for normalised slow extension stiffness (Figure 7.20) although a one-way ANOVA showed that these differences were not significant ($F(2,26) = 1.064$, $p = 0.360$, $\omega^2 = 0.000$).
Normalised slow flexion stiffness was not normally distributed and therefore a boxplot (Figure 7.21) was used to demonstrate differences between groups. The TKA group showed slightly higher (median = 1.092) normalised slow flexion stiffness scores than the control group (median = 1.083) but the OA group appeared much lower (median = 0.689). Variances however were large (Figure 7.21) and a Kruskall-Wallis test showed that differences between groups in normalised slow flexion stiffness were not significant ($\chi^2 = 2.638$, df = 2, p = 0.267).
7.7.3 Stiffness threshold angles

The two points during flexion-extension which are of interest were 1) the threshold angle at which flexion stiffness was seen to increase significantly and 2) the threshold angle at which extension stiffness was seen to increase significantly.

All angle variables were normally distributed (Appendix 4) and were presented using the mean. All angle variables also met the assumption of homogeneity of variance (Appendix 5). No significant differences between genders were observed (Appendix 6) and therefore gender was not considered as a confounding variable. Figure 7.22 and Figure 7.23 show the mean threshold extension and flexion stiffness angle by group at each of fast and slow velocities. Error bars indicate ± 1.sd.

Figure 7.21 Normalised slow flexion stiffness by group
Figure 7.22 Threshold flexion and extension stiffness angles at fast velocity

Figure 7.22 shows that the threshold angle of flexion stiffness at a fast velocity was higher for the control group than either the OA or TKA groups. Interestingly the control group also showed a higher threshold angle for extension stiffness. A one-way ANOVA showed that differences in the fast threshold flexion stiffness angle were significant (F(2,28) = 7.780, p = 0.002, $\omega^2 = 0.318$). Differences between groups the fast threshold extension stiffness angle were not significant (F(2,27) = 2.439, p = 0.108, $\omega^2 = 0.093$). Figure 7.23 also shows that this pattern was repeated for the tests at slow velocity.
A one-way ANOVA showed that there was no significant difference between groups in the slow threshold extension stiffness angle (F(2,28) = 1.266, p = 0.299, $\omega^2 = 0.018$). There were however highly significant differences in the slow threshold flexion stiffness angle (F(2,29) = 9.962, p = 0.001, $\omega^2 = 0.374$).

Post-hoc analysis (Table 7.14) showed that the control group demonstrated highly significant higher flexion angles than either the OA group or the TKA group. There were no differences between the TKA and OA groups.
Table 7.14 Results of the post-hoc Tukeys tests (p-values) for fast and slow threshold flexion stiffness angles.

<table>
<thead>
<tr>
<th></th>
<th>Fast flexion</th>
<th>Slow flexion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control vs OA</td>
<td>0.009*</td>
<td>0.002*</td>
</tr>
<tr>
<td>Control vs TKA</td>
<td>0.004*</td>
<td>0.002*</td>
</tr>
<tr>
<td>OA vs TKA</td>
<td>0.982</td>
<td>0.752</td>
</tr>
</tbody>
</table>

7.7.4 Normalised threshold stiffness angle

Data was then normalised to the maximum passive flexion angle (flexion stiffness) and to the maximum range of motion (passive flexion – passive extension). Data was normally distributed (Appendix 4) (with the exception of slow extension threshold stiffness angle) and met the assumption of homogeneity of variance (Appendix 5). Therefore differences between groups were determined using a one-way ANOVA (with the exception of slow extension which was analysed using the Kruskall-Wallis test).

Figure 7.24 shows the normalised threshold flexion and extension stiffness angles at a fast velocity. Differences between groups were now less apparent.
Figure 7.24 Normalised threshold fast extension stiffness angles by group

Figure 7.25 shows the normalised threshold flexion and extension stiffness angles at slow velocity. A similar pattern to the fast velocity could be seen.
Once the data was normalised, there were no significant differences between the groups (normalised fast flexion stiffness angle, $F(2,26) = 1.438, p = 0.256, \omega^2 = -0.019$; normalised slow flexion stiffness angle, $F(2,27) = 1.667, p = 0.066, \omega^2 = 0.020$). Although it appears that the OA group are closer to full available extension before maximal extension stiffness occurs at fast velocity, this was not significant ($F(2,25) = 1.298, p = 0.291, \omega^2 = 0.021$). There were no significant differences in slow extension stiffness angle ($\chi^2 = 0.719, p = 0.698$).
7.7.5 Passive resistive torque

The value of the passive resistive torque at the point where stiffness significantly increased was also recorded. All variables were normally distributed with the exception of slow extension stiffness torque (Appendix 4). All variables demonstrated homogeneity of variance (Appendix 5) and therefore the ANOVA was used to detect differences between groups (with the exception of slow extension stiffness torque). No difference between gender were detected for any variable (Appendix 6) and therefore gender was not considered as a confounding variable. Figure 7.26 to Figure 7.29 show the mean torque at the point where extension/flexion stiffness occurs at both fast and slow velocities. The negative sign on the flexion graphs indicates the direction of the torque. A positive value indicate that the resistance was opposing extension of the knee and a negative value indicates that the passive resistance was opposing flexion of the knee.
Although Figure 7.26 showed that the control group had the highest fast extension stiffness threshold torque (6.003Nm ± 8.109), followed by the OA group (3.896Nm ± 4.222) and the lowest was the TKA group (2.702Nm ± 6.600), the one-way ANOVA indicated that these differences were not significant (F(2,27) = 0.619, p = 0.547, $\omega^2 = -0.028$).

Figure 7.27 showed that the fast flexion stiffness threshold torque was lowest in the OA group (-0.168Nm ± 5.622), followed by the TKA group (-3.472 ± 5.113). Again, it appears that the control group had the highest torque (-4.444Nm ± 4.910). These differences however were not significant (F(2,28) = 1.452, p = 0.252, $\omega^2 = 0.030$).
Figure 7.27 Fast flexion threshold stiffness torque by group

Figure 7.28 and Figure 7.29 show the threshold torque value at extension and flexion stiffness during slow velocities. Slow extension stiffness torque was not normally distributed and is therefore presented as median.

The TKA group had the highest resistive torque in slow extension (-3.232 ± 5.74). The control had a median of -1.734 (± 5.09) and the OA group was very similar at -1.722 (± 5.63).
A Kruskall-Wallis test showed that differences in slow extension threshold torque were not significant ($\chi^2 = 2.512$, df = 2, $p = 0.285$).

Figure 7.29 also shows that the TKA group had a higher threshold torque at slow flexion stiffness however these differences were not statistically significant ($F(2,27) = 0.394$, $p = 0.678$, $\omega^2 = -0.042$).
The relationship between subjective and objective measures of stiffness were explored in order to provide further information on the validity of patient reported measures of stiffness.

Spearman’s rho correlation coefficients were calculated between patient reported (WOMAC stiffness and VAS stiffness) and objective measures of stiffness (stiffness, and normalised stiffness; threshold stiffness angles and normalised threshold stiffness angles).
Spearmans $\rho$ correlation coefficients revealed no significant associations ($p > 0.05$) between self-reported and objective measures of stiffness (Table 7.15).

Table 7.15 Measures of association between self-reported stiffness and objective stiffness

<table>
<thead>
<tr>
<th>Stiffness variable</th>
<th>WOMAC stiffness $\rho$ (p-value)</th>
<th>VAS stiffness $\rho$ (p-value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fast extension stiffness</td>
<td>-0.136 (0.491)</td>
<td>-0.109 (0.580)</td>
</tr>
<tr>
<td>Fast flexion stiffness</td>
<td>0.083 (0.667)</td>
<td>0.017 (0.930)</td>
</tr>
<tr>
<td>Slow extension stiffness</td>
<td>-0.181 (0.348)</td>
<td>-0.122 (0.530)</td>
</tr>
<tr>
<td>Slow flexion stiffness</td>
<td>-0.103 (0.589)</td>
<td>-0.120 (0.528)</td>
</tr>
<tr>
<td>Normalised fast extension stiffness</td>
<td>-0.238 (0.223)</td>
<td>-0.170 (0.388)</td>
</tr>
<tr>
<td>Normalised fast flexion stiffness</td>
<td>0.053 (0.785)</td>
<td>-0.045 (0.816)</td>
</tr>
<tr>
<td>Normalised extension stiffness slow</td>
<td>-0.226 (0.238)</td>
<td>-0.174 (0.366)</td>
</tr>
<tr>
<td>Normalised slow flexion stiffness</td>
<td>-0.200 (0.289)</td>
<td>-0.228 (0.226)</td>
</tr>
</tbody>
</table>

Spearman’s $\rho$ correlation coefficient revealed no significant associations ($p > 0.05$) between self-reported measures of stiffness and the threshold stiffness angle (Table 7.16).
Table 7.16 Measures of association between self-reported stiffness and threshold stiffness angles

<table>
<thead>
<tr>
<th>Threshold stiffness angle</th>
<th>WOMAC stiffness rho (p-value)</th>
<th>VAS stiffness rho (p-value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fast threshold extension stiffness angle</td>
<td>0.017 (0.932)</td>
<td>-0.201 (0.304)</td>
</tr>
<tr>
<td>Fast threshold flexion stiffness angle</td>
<td>-0.015 (0.937)</td>
<td>-0.200 (0.297)</td>
</tr>
<tr>
<td>Slow threshold extension stiffness angle</td>
<td>0.166 (0.389)</td>
<td>-0.167 (0.386)</td>
</tr>
<tr>
<td>Slow threshold flexion stiffness angle</td>
<td>-0.123 (0.518)</td>
<td>-0.204 (0.279)</td>
</tr>
<tr>
<td>Normalised fast threshold extension stiffness angle</td>
<td>0.138 (0.483)</td>
<td>-0.057 (0.772)</td>
</tr>
<tr>
<td>Normalised fast threshold flexion stiffness angle</td>
<td>0.132 (0.495)</td>
<td>0.101 (0.603)</td>
</tr>
<tr>
<td>Normalised slow threshold extension stiffness angle</td>
<td>0.283 (0.136)</td>
<td>0.007 (0.971)</td>
</tr>
<tr>
<td>Normalised slow threshold flexion stiffness angle</td>
<td>0.073 (0.700)</td>
<td>0.106 (0.579)</td>
</tr>
</tbody>
</table>

7.9 Relationship between stiffness and function

This section will look at the potential relationship between stiffness (both patient reported and objective) and measures of function (both patient reported and performance based). As the hypothesis was only particularly interested in the association between stiffness and function in TKA subjects and differences were found in patients reported stiffness between groups, this analysis was limited to the TKA group.
7.9.1 Patient reported stiffness and function

The relationships between participant reported stiffness (the VAS stiffness score and the WOMAC stiffness score) and the measures of function (WOMAC function, SF-12 PCS, TUG, stair ascent, walking speed and normalised LEP) were determined. As data were not normally distributed (Appendix 4), Spearmans $\rho$ was calculated.

VAS stiffness showed a significant moderate correlation ($\rho > 0.5$) with WOMAC function but no other significant correlations (Table 7.17). WOMAC stiffness however showed a significant strong correlation ($\rho = 0.7$ to 0.89) with WOMAC function and significant moderate correlations with the TUG, stair ascent/descent and walking speed.

Table 7.17 Measures of association between self-reported stiffness and function

<table>
<thead>
<tr>
<th>Function variable</th>
<th>VAS stiffness</th>
<th>WOMAC stiffness</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$\rho$</td>
<td>$\rho^2$</td>
</tr>
<tr>
<td>WOMAC function</td>
<td>0.577</td>
<td>0.333</td>
</tr>
<tr>
<td>SF-12 PCS</td>
<td>-0.362</td>
<td>0.131</td>
</tr>
<tr>
<td>TUG</td>
<td>0.258</td>
<td>0.066</td>
</tr>
<tr>
<td>Stair ascent/descent</td>
<td>0.317</td>
<td>0.100</td>
</tr>
<tr>
<td>Walking speed</td>
<td>-0.373</td>
<td>0.139</td>
</tr>
<tr>
<td>Normalised LEP</td>
<td>-0.177</td>
<td>0.031</td>
</tr>
</tbody>
</table>

Increased stiffness was associated with greater functional limitations (WOMAC function), slower TUG times, slower stair ascent/descent times and slower walking speed. Scatterplots of self-reported stiffness and function can be found in Appendix 9.
7.9.2 Objective measures of stiffness and function

Relationships between the raw objective stiffness values in each of the three phases and the functional outcome measures was determined using the Spearmans $\rho$ (Table 7.18)

Table 7.18 Measures of association ($\rho$) between raw stiffness variables and function

<table>
<thead>
<tr>
<th>Stiffness values</th>
<th>WOMAC function</th>
<th>SF12-PCS</th>
<th>TUG</th>
<th>Stair ascent</th>
<th>Walking speed</th>
<th>normalised LEP</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Fast</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Extension</td>
<td>-0.026</td>
<td>0.157</td>
<td>0.074</td>
<td>0.136</td>
<td>0.077</td>
<td>0.207</td>
</tr>
<tr>
<td>midrange</td>
<td>-0.105</td>
<td>0.163</td>
<td>0.018</td>
<td>-0.057</td>
<td>-0.191</td>
<td>-0.122</td>
</tr>
<tr>
<td>Flexion</td>
<td>-0.030</td>
<td>-0.15</td>
<td>0.180</td>
<td>0.032</td>
<td>-0.174</td>
<td>0.001</td>
</tr>
<tr>
<td><strong>Slow</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Extension</td>
<td>-0.063</td>
<td>0.300</td>
<td>-0.148</td>
<td>0.030</td>
<td>0.005</td>
<td>0.134</td>
</tr>
<tr>
<td>Midrange</td>
<td>-0.262</td>
<td>0.320</td>
<td>-0.235</td>
<td>-0.304</td>
<td>0.093</td>
<td>0.195</td>
</tr>
<tr>
<td>Flexion</td>
<td>-0.278</td>
<td>0.209</td>
<td>-0.292</td>
<td>-0.318</td>
<td>0.065</td>
<td>0.270</td>
</tr>
</tbody>
</table>

None of the stiffness values showed any significant correlations ($p > 0.05$) with measures of function.

Normalised stiffness values were also analysed for relationships with measures of function (Table 7.19).
Table 7.19 Measures of association (\(\rho\)) between normalised stiffness variables and function

<table>
<thead>
<tr>
<th>Normalised stiffness values</th>
<th>WOMAC function</th>
<th>SF12-PCS</th>
<th>TUG</th>
<th>Stair ascent</th>
<th>Walking speed</th>
<th>normalised LEP</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Fast</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Extension</td>
<td>-0.098</td>
<td>0.281</td>
<td>0.010</td>
<td>0.088</td>
<td>0.213</td>
<td>0.280</td>
</tr>
<tr>
<td>midrange</td>
<td>-0.105</td>
<td>0.163</td>
<td>0.018</td>
<td>-0.057</td>
<td>-0.191</td>
<td>-0.122</td>
</tr>
<tr>
<td>Flexion</td>
<td>-0.121</td>
<td>0.056</td>
<td>0.120</td>
<td>-0.048</td>
<td>-0.210</td>
<td>0.131</td>
</tr>
<tr>
<td><strong>Slow</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Extension</td>
<td>-0.154</td>
<td>0.366</td>
<td>-0.167</td>
<td>-0.033</td>
<td>0.061</td>
<td>0.240</td>
</tr>
<tr>
<td>Midrange</td>
<td>-0.262</td>
<td>0.320</td>
<td>-0.235</td>
<td>-0.304</td>
<td>0.093</td>
<td>0.195</td>
</tr>
<tr>
<td>Flexion</td>
<td>\textbf{-0.364*}</td>
<td>0.275</td>
<td>-0.343</td>
<td>-0.358</td>
<td>0.106</td>
<td>0.362</td>
</tr>
</tbody>
</table>

* \(p \leq 0.05\)

WOMAC function showed a low, significant relationship with slow flexion stiffness (\(\rho = -0.364, p = 0.048\)). TUG, stair ascent/descent and normalised LEP also showed low associations although the \(p\)-value for these three variables was just outside the alpha level (TUG \(\rho = -0.343, p = 0.064, \rho^2 = 0.117\); stair ascent/descent \(\rho = -0.358, p = 0.052, \rho^2 = 0.128\); normalised LEP \(\rho = 0.362, p = 0.054, \rho^2 = 0.131\)). Scatterplots of these relationships can be found in Appendix 9. These scatterplots supported the suggestion that there may be an association between slow flexion stiffness and function.

The relationship between the angle at which flexion and extension stiffness was seen to increase (stiffness threshold angle) and measures of function was also explored (Table 7.20).
Table 7.20 Measures of association ($\rho$) between stiffness threshold angle and function

<table>
<thead>
<tr>
<th>Threshold stiffness angle</th>
<th>WOMAC function</th>
<th>SF12-PCS</th>
<th>TUG</th>
<th>Stair ascent</th>
<th>Walking speed</th>
<th>Normalised LEP</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Fast</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Extension</td>
<td>-0.188</td>
<td>-0.104</td>
<td>-0.269</td>
<td>-0.110</td>
<td>.083</td>
<td>0.313</td>
</tr>
<tr>
<td>Flexion</td>
<td>0.000</td>
<td>-0.258</td>
<td>0.082</td>
<td>0.016</td>
<td>-0.099</td>
<td><strong>0.626</strong></td>
</tr>
<tr>
<td><strong>Slow</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Extension</td>
<td>-0.160</td>
<td>-0.082</td>
<td>-0.253</td>
<td>-0.280</td>
<td>-0.140</td>
<td>0.418</td>
</tr>
<tr>
<td>Flexion</td>
<td>-0.171</td>
<td>-0.363</td>
<td>-0.170</td>
<td>-0.231</td>
<td>-0.231</td>
<td><strong>0.566</strong></td>
</tr>
</tbody>
</table>

Normalised LEP was shown to have a significant moderate relationship with fast flexion stiffness threshold angle ($\rho = 0.626$, $p = 0.022$, $r^2 = 0.392$) and slow flexion stiffness threshold angle ($\rho = 0.566$, $p = 0.044$, $r^2 = 0.320$). The positive nature of the relationship indicated that larger flexion values are associated with better scores for leg extensor power.

The relationship between normalised threshold stiffness angles and function was also explored (Table 7.21).

Table 7.21 Measures of association ($\rho$) between normalised threshold stiffness angles and function

<table>
<thead>
<tr>
<th>Normalised Threshold stiffness angle</th>
<th>WOMAC function</th>
<th>SF12-PCS</th>
<th>TUG</th>
<th>Stair ascent</th>
<th>Walking speed</th>
<th>Normalised LEP</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Fast</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Extension</td>
<td>0.094</td>
<td>-0.038</td>
<td>-0.011</td>
<td>0.264</td>
<td>-0.184</td>
<td>-0.022</td>
</tr>
<tr>
<td>Flexion</td>
<td>0.254</td>
<td><strong>0.566</strong></td>
<td>0.643</td>
<td>-0.564</td>
<td></td>
<td><strong>0.225</strong></td>
</tr>
<tr>
<td><strong>Slow</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Extension</td>
<td>0.160</td>
<td>-0.093</td>
<td>-0.011</td>
<td>-0.082</td>
<td>-0.366</td>
<td>0.143</td>
</tr>
<tr>
<td>Flexion</td>
<td>0.281</td>
<td>0.231</td>
<td>0.352</td>
<td><strong>0.544</strong></td>
<td>-0.294</td>
<td>0.082</td>
</tr>
</tbody>
</table>
The TUG was shown to have a significant moderate correlation with normalised fast flexion threshold stiffness angle (\(\rho = 0.566, p = 0.044, r^2 = 0.320\)). Stair ascent/descent was also shown to have a significant moderate correlation with normalised stiffness angle (\(\rho = 0.643, p = 0.018, r^2 = 0.413\)). A moderate correlation was also seen for stair ascent/descent and slow flexion stiffness threshold angle but the p-value lay just outside significance (\(\rho = 0.544, p = 0.055\)). Walking speed also showed a significant moderate correlation (\(\rho = -0.564, p = 0.045, r^2 = 0.318\)) with normalised fast flexion stiffness threshold angle. Positive relationships between angle and TUG and stair ascent/descent suggested that larger angles are associated with longer times for the activities (i.e. slower speeds). A negative relationship between angle and walking speed suggests that higher angles are associated with slower walking speeds. Scatterplots of potential relationships can be found in Appendix 9.

7.10 Post-hoc sample size calculations

Using the mean and s.d. values from the control and TKA groups for the objective stiffness measures, sample size calculations were undertaken (Lenth, 2009) to predict the number of participants per group that would have been required in order to detect differences between the TKA and control group with a probability of 0.95 and a power of 0.8. The results of the analysis for the slow extension and flexion stiffness, both raw and normalised are summarised in Table 7.22.
Table 7.22 Sample size calculations for differences in stiffness

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean diff (TKA – control)</th>
<th>sd TKA group</th>
<th>sd control group</th>
<th>Effect size</th>
<th>Sample size per group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Slow flexion stiffness</td>
<td>0.15</td>
<td>0.339</td>
<td>0.225</td>
<td>0.53</td>
<td>59</td>
</tr>
<tr>
<td>Slow extension stiffness</td>
<td>0.275</td>
<td>0.471</td>
<td>0.188</td>
<td>0.84</td>
<td>28</td>
</tr>
<tr>
<td>Normalised slow flexion stiffness</td>
<td>0.277</td>
<td>0.754</td>
<td>0.470</td>
<td>0.45</td>
<td>82</td>
</tr>
<tr>
<td>Normalised slow extension stiffness</td>
<td>0.537</td>
<td>1.059</td>
<td>0.480</td>
<td>0.70</td>
<td>39</td>
</tr>
</tbody>
</table>

These figures confirmed the suggestion that the study was underpowered but also suggested that the effect sizes were large enough to show significant differences in a larger sample size. A sample size of 164 would be large enough to detect differences in flexion stiffness between a TKA and control group.
8 Discussion

This chapter will consider the results in greater depth and discuss them with reference to previously published work. Although it was not the aim of the study to compare outcomes between groups, it was useful to consider differences between groups in order to determine whether the results based upon this small sample could be generalised to a wider TKA population. Furthermore, previously published work has identified that many TKA patients continue to experience functional limitations even at one-year post-surgery, when rehabilitation is generally agreed to have reached a plateau. The rationale for the study was partly developed based upon these premises; therefore, it was useful to determine whether these assumptions still held true. Thus the discussion will begin with a consideration of the participants and the general outcomes of surgery. The main focus of the study was to explore stiffness at the knee joint and the chapter will go on to consider the results of the analysis of differences in stiffness between groups and the association between stiffness and function. Finally the chapter will consider; the limitations, sources of error and clinical implications for the study.

8.1 Participant characteristics

In order to be able to determine whether differences in outcome and stiffness could be attributed to the independent variable, it was first important to determine whether the samples were broadly similar in terms of general characteristics. If any differences were observed then the variable was considered as a co-variate in the analysis. There were no significant differences in age, height, weight or other anthropometric variables. The gender ratio however was significantly different between groups. The OA and TKA groups were broadly similar in proportion (63%
males in the OA group and 73% in the TKA group) however the control group had a significantly larger proportion of female volunteers (75%). The ratio of male: females undergoing TKA in Scotland in 2007-08 was 42:58 (Scottish Arthroplasty Project, 2009). The proportion of male patients who volunteered for this study was therefore not necessarily representative of a wider TKA population. Previous studies (Myles et al, 2001) have also reported a higher number of female volunteers in the control group. The reasons for this were not entirely clear although the recruitment strategy was likely to have played a significant role. In the current study, volunteers were recruited from local community groups. Two of the groups had a much higher proportion of female attendees which could have accounted for a higher number of females volunteering for the study. Participants were also recruited using email distribution lists and newsletters of the QMU research group, the ‘Centre for the Older Persons Agenda’. Although the proportion of males and females in this target group was not known, the number of males and females recruited this way was more evenly split. In retrospect, the community groups who were the initial target were not ideal given their gender proportions. As a result of the differences in gender proportions in the current study, all variables were checked for potential differences between genders. Differences however were found only in the TUG and stair/ascent descent test. In these variables, gender was considered as a potential confounding variable and was taken into account when comparing differences between groups. Although differences between genders were not significant for most variables, it was possible that the small sample sizes could have influenced the significance of any differences. Effect sizes however in general were small, supporting the conclusion that if a true difference existed, the effect was small. The median age of patients
undergoing TKA in Scotland in 2007-08 was 70 years (Scottish Arthroplasty Project, 2009) suggesting that the age of the participants in this study was representative of the TKA population. Height and weight of study participants is not often recorded but a review of studies that did showed that the BMI of participants in the current study were broadly similar (Farquhar, Reisman, & Snyder-Mackler, 2008; Fisher et al, 2007; Halket et al., 2008; van der Linden et al., 2007).

8.2 Clinical knee examination

As expected, the current study found significant differences between groups in maximum knee flexion (both active and passive) as well as passive extension. The control group had significantly greater flexion than both the OA and TKA groups. There were no differences between the OA and TKA group in any range of motion variable. The results agreed with previous literature that has found that even at 1 year post TKA, patients had significantly less flexion than age matched controls (Myles et al, 2001; Walsh et al., 1998). However the results presented in this thesis also showed little difference between the OA group and the TKA group suggesting that patients undergoing TKA could expect to see little improvement on their pre-operative range of motion even at 1 year post-surgery. This also agreed with Myles et al (2001) who found that although the difference between pre-op and 18-24 months was statistically significant, on average, the post-op improvement was only 2% of the original pre-op values. Direct comparisons with Myles et al (2001) must be viewed with caution however, as their study reported on a series of patients undergoing TKA with a different type of prosthesis (the LCS$^{21}$) and also reported lower pre-operative values.

\[21\text{ DuPuy, Warsaw, IN}\]
for active flexion and active excursion (active flexion was 104° compared with 110° reported in this study). Participants in the current study received either a Kinemax\textsuperscript{22} prosthesis or a newer prosthesis, the Triathlon\textsuperscript{22}, which the manufacturers have claimed more closely mimics the natural motion of the knee and thus provides greater range of motion without compromising stability (Stryker Orthopaedics, 2009). It was therefore interesting that the current study found that at 1 year post-op, there were no differences in knee range of motion between prostheses types and that, on average, the TKA group had similar knee flexion and extension to those who were on the waiting list for surgery. It was also difficult to compare the results of the TKA group directly with the range of motion from previously published data. Since the shift in emphasis towards patient reported outcomes, few studies have considered range of motion and even fewer have compared range with that of an age matched control group.

Table 8.1 provides a summary of studies that have reported range of motion data within the last 15 years. Very few have stated the prosthesis used, making it difficult to hypothesise as to whether manufacturers claims for improved range of motion could be supported. Nevertheless, the data from the current study indicated that range of motion in patients who were 1 year post-TKA was similar or better than previously published reports (Frost, Lamb, & Robertson, 2002; Jogi, Kramer, & Birmingham, 2005; Lamb & Frost, 2003; MacDonald et al., 2000; Mizner, Petterson, & Snyder-Mackler, 2005; Myles et al, 2001; Walsh et al, 1998). Only two, more recently published, studies (Rossi et al., 2006; Yoshida et al., 2008) reported better range of motion than the current study. Both of these studies were US based where

\textsuperscript{22} Stryker Orthopaedics, NJ
outcomes have previously been shown to be better than in the UK (Lingard et al, 2004). Furthermore, in the study by Yoshida et al. (2008), the patients were considerably younger (61 years compared to 69 in the current study) which may have influenced the results. All patients (with the exception of 1) in the study by Rossi et al. (2006) received post-discharge physiotherapy (compared to only 1 in the current study) which may also have influenced the range of motion.

Table 8.1 Summary of studies within the last 15 years who have reported range of motion data

<table>
<thead>
<tr>
<th>Study</th>
<th>N</th>
<th>Pre-op</th>
<th>Post-op</th>
<th>Prosthesis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current</td>
<td>15</td>
<td>Passive range 6°-110°</td>
<td>Passive range 2°-115°</td>
<td>Kinemax or Triathlon</td>
</tr>
<tr>
<td>Yoshida et al (2008)</td>
<td>12</td>
<td>NA</td>
<td>-1.2°-124°</td>
<td>Not stated</td>
</tr>
<tr>
<td>Rossi et al (2006)</td>
<td>11</td>
<td>NA</td>
<td>2° to 121° at 17 months post-op</td>
<td>Not stated</td>
</tr>
<tr>
<td>Mizner, Petterson &amp; Snyder-Mackler (2005)</td>
<td>40</td>
<td>3°-119°</td>
<td>1°-116° at 6 months post-op</td>
<td>Not stated</td>
</tr>
<tr>
<td>Lamb &amp; Frost (2003)</td>
<td>79</td>
<td>111° flexion</td>
<td>100° at 6 months</td>
<td>Not stated</td>
</tr>
<tr>
<td>Jogi, Kramer &amp; Birmingham (2003)</td>
<td>276</td>
<td>106° range of motion</td>
<td>99° at 6 months</td>
<td>Not stated</td>
</tr>
<tr>
<td>Frost et al (2002)</td>
<td>27</td>
<td>106° flexion</td>
<td>102° flexion at 12 months</td>
<td>Not stated</td>
</tr>
<tr>
<td>Myles et al (2001)</td>
<td>50</td>
<td>-6° – 104°</td>
<td>1°-97° at 18-24 months post-op</td>
<td>LCS</td>
</tr>
<tr>
<td>MacDonald et al (2000)</td>
<td>120</td>
<td>NA</td>
<td>112° flexion at 12 months post-op</td>
<td>AMK or Genesis II</td>
</tr>
<tr>
<td>Walsh et al (1998)</td>
<td>29</td>
<td>NA</td>
<td>0.3° – 112° at 12 months post-op</td>
<td>Not stated</td>
</tr>
</tbody>
</table>

As the data in Table 8.1 shows, few studies have reported normal values for age matched healthy populations, but data from the current study showed similar results to Yoshida et al (2008) - TKA patients achieved around 91% of the maximum active
flexion and 90% of the maximum active range experienced by healthy age matched controls. These results were better than those reported by Myles et al (2001) who found that at 18-24 months post-TKA patients reported a 29% reduction in maximum active flexion and a 31% reduction in active range compared to controls.

Although the current study did not define stiffness as a lack of range of motion, the literature has often referred to stiffness as a limitation in available range of movement (Kim, Nelson, & Lotke, 2004; Fisher et al, 2007) and therefore it was interesting to compare ‘stiffness’ incidence using these criteria. The definition of a “stiff knee” using range of motion data has varied however. Kim, Nelson and Lotke (2007) used the presence of a flexion contracture of ≥ 15° and/or ≤ 75° of flexion. Based on these criteria they quoted an incidence of stiffness of 1.3% whereas Fisher et al (2007), who used the criteria of < 90° flexion, quoted an incidence rate of 6.9%.

In the current study, stiffness rates were comparable to those of Fisher et al. (2007) (6.7% of TKA patients (n = 1) had a range of motion of < 90°). No participants had a flexion contracture of ≥ 15° and only 1 participant had < 90° flexion.

Ritter et al (2008a) concluded that outcomes in TKA were significantly compromised in those with flexion of less than 118° and that the optimum ROM was 128°-132°. This was interesting as all studies in Table 8.1 reported a maximum knee flexion below these values and only 5.3 (0.1%) of the 5556 knees reviewed by Ritter et al (2008a) actually achieved a ROM in this range. Myles et al (2001) disagreed, concluding that non-weight bearing range of motion was not necessarily an indicator of functional joint range. The results of the current study showed that although patients with TKA did not appear to improve their ROM significantly compared to a pre-operative OA group, improvements in both patient perceptions of function and
performance based measures of function could be seen. It could therefore be concluded that the results of the current study disagreed with those of Ritter et al (2008a) and supported the hypothesis that function is influenced by factors other than ROM.

8.3 Outcomes of TKA

This study is one of a small number that have used both patient reported and performance based measures of outcome to compare outcomes of patients at 1 year post-TKA with a healthy age-matched control group. Using the search terms ‘control’ and ‘tka’ and/or ‘total knee arthroplasty’ and/or ‘total knee replacement’ in the databases of Medline and Cinahl, only 7 articles could be found which reported control data and TKA outcomes at a minimum of 1 year post-TKA (Boonstra, De Waal Malefit, & Verdonschot, 2008; Farquhar, Reisman, & Snyder-Mackler, 2008; Finch et al, 1998; Myles et al, 2001; Rossi et al, 2006; Walsh et al, 1998; Yoshida et al, 2008). Three of these articles were over 8 years old and reported on prostheses which may no longer have been in common use. Furthermore, two of the articles, Finch et al (1998) and Walsh et al (1998), reported slightly different aspects of the same study and not all studies reported clinical outcomes, as well as patient reported outcomes and performance based outcomes.

There have been few previous studies which have compared patient reported outcomes between TKA patients and controls and in the few that have differences in reporting methods made it difficult to compare studies. These differences include for example, different outcome measures or even differences in interpretation of the same outcome measure, i.e. differences in reporting of the WOMAC scores. Several studies that reported the WOMAC in patients 1 year post-TKA (Bachmeier et al,
deviated from the original scoring system (Bellamy, 2000) used in the current study. Thus normalised scores (0-100 scale as described in section 6.7.1) were used in order allow between study comparisons to be made.

8.3.1 Patient reported outcomes

This study found that patient reported outcomes (WOMAC and SF-12) demonstrated (as expected) that the OA group had significantly worse pain and more functional limitations than either the TKA or control groups. No differences in pain, function were found between the TKA and control groups.

One of the main goals of TKA surgery was to reduce pain. The results of the current study agreed with many previous studies that have shown that pain was significantly improved on the pre-operative (OA) status (Bachmeier et al, 2001; Dickstein et al, 1998; Hawker et al, 1998; Heck et al, 1998; Jogi, Kramer, & Birmingham, 2005; Lingard et al, 2004; Swinkels, Newman, & Allain, 2009). The finding of no difference in pain scores between TKA and controls in the current study agreed with a recent study (Boonstra, De Waal Malefit, & Verdonschot, 2008) but was however in contrast to an earlier study (Finch et al, 1998) which found that although pain was significantly improved post-operatively, TKA patients continued to report more pain than age matched healthy controls. The participants in the current study however appeared to have less pain at 1 year post-TKA (on a WOMAC scale) than previously reported (Finch et al, 1998; Jogi, Kramer, & Birmingham, 2005; Lingard et al, 2004) which may explain why the current study found no difference in WOMAC pain scores between TKA and control subjects. The results of the current study were thus
encouraging, suggesting that patient experiences of pain following TKA may be improving. It is possible however that those who volunteered to take part in this study may not have been representative of the wider TKA population and the small sample may have been biased towards those with a better outcome.

In the current study, unsurprisingly, the OA group had significantly worse WOMAC function scores than both the TKA and control group. Furthermore, post-hoc testing also showed that although the TKA and control group demonstrated significant differences at the 0.05 level, once the Bonferroni correction had been applied (as recommended by Vincent (2005), the p-value of 0.028 was no longer significant. Bonferroni adjustments were made to reduce the risk of making a Type I error that was associated with several sets of comparisons. However, as Perneger (2005) pointed out, a reduction in the risk of a Type I error unavoidably increased the risk of a type II error. Perneger (2005) also went on to argue that Bonferroni adjustments should only be really made when the same test is repeated in many subsamples or when searching for association without first establishing hypotheses. They concluded by recommending that all possible interpretations of the results were discussed without recourse to the Bonferroni correction. With this in mind, the difference between the TKA and control groups was considered not only with respect to the statistical significance of the differences but also with respect to the Minimal Clinical Important Difference (MCID). Studies have shown that a difference of 10-12 points on the WOMAC scales indicated a clinically significant difference (Angst, Aeschlimann, & Stucki, 2001; Ehrich et al., 2000). Thus according to this research, the difference in the current study between TKA and control groups of 14.8 points (on a 0-100 scale) may in fact have represented a clinically important difference.
This agreed with the other studies (Table 8.2) who found significant differences between TKA and control groups in self-reported functional ability (Finch et al., 1998; Boonstra, de Waal Malefit & Verdonshot, 2008). Similar to previous studies (Parent & Moffat, 2002), large effect sizes were observed for all WOMAC dimensions indicating that the small sample sizes were more likely to be the reason for the lack of statistical significance rather than the lack of effect.

Table 8.2 WOMAC function scores in 1 year post-TKA and control subjects

<table>
<thead>
<tr>
<th>Study</th>
<th>Post-TKA</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current</td>
<td>14.8</td>
<td>0</td>
</tr>
<tr>
<td>Finch (1998)</td>
<td>19.7</td>
<td>1.35</td>
</tr>
<tr>
<td>Bachmeier (2001)</td>
<td>21.8</td>
<td>NA</td>
</tr>
<tr>
<td>Lingard (2004)</td>
<td>30</td>
<td>NA</td>
</tr>
<tr>
<td>Van der Linden (2007)</td>
<td>24.4</td>
<td>NA</td>
</tr>
<tr>
<td>Boonstra (2008)</td>
<td>23.1</td>
<td>5.3</td>
</tr>
<tr>
<td>Swinkels (2009)</td>
<td>32.9</td>
<td>NA</td>
</tr>
</tbody>
</table>

Participants in the current study were also asked to report on any stiffness in the knee joint. Ninety-seven out of 114 (85%) participants reported some sensation of stiffness during movement (based on the VAS reports). The OA group had significantly worse self-perceived stiffness than either the TKA or control groups. Interestingly, only 16 out of 35 (46%) reported stiffness on wakening or when resting later in the day (the WOMAC scales). Although the WOMAC questionnaire also included a stiffness component, these scores have not always been included in

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23 18-24 months post-TKA
24 16 months post-TKA
reports of WOMAC scores, making it difficult to compare these results with other studies. Two studies have been mentioned previously that have compared WOMAC scores in a TKA population with controls (Finch et al, 1998; Boonstra, De Waal Malefit and Verdonschot, 2008), but only Finch et al (1998) reported the stiffness scores. At 1 year post-op, Finch et al (1998) reported a mean stiffness score of 4.9 out of a possible 20 and 0.6 in a group of age-matched healthy controls. These differences were statistically significant. In the current study the WOMAC stiffness score of the OA group (median = 3 out of 8) was higher than the TKA or control groups (median = 0) but differences were not found to be significant. However, when an outlier in the control group was removed, statistically significant differences were found (the OA group had significantly higher stiffness than the control group). Other studies have reported pre-operative mean stiffness scores of 4.1 (Heck et al, 1998) and 4.9 (Swinkels, Newman, & Allain, 2009) (out of 8) which were similar to the current study. However, similar to the pain and function scores, the stiffness scores at 1 year post-op in the current study were better than those in other studies (Finch et al, 1998; Heck et al., 1998; Swinkels, Newman & Allain, 2009). This may explain why the current study found no significant difference between the TKA and the control group. WOMAC stiffness scores in the current study also demonstrated higher levels of variance than the other WOMAC dimensions which together with the small sample size may also have contributed to the lack of statistical significance.

The variability of the stiffness scores may have been influenced by the participants' understanding of stiffness. In addition to rating the severity of knee joint stiffness, participants were also asked to indicate words which described their stiffness. They were offered a range of words similar to those used in a previous study on
rheumatoid arthritis (Rhind, 1987) and which contained words which described
difficulty with movement, pain and sensations. Similar to Rhind (1987), the majority
of participants in the current study used words from more than 1 category. There was
a significant association between the severity of self-perceived stiffness and the
number of words used – the worse the self-perceived stiffness, the greater the
number of words selected was. Of those who reported stiffness, one third (35%) used
word(s) from the pain category to describe their stiffness although only 19% of the
words offered were related to pain. This finding concurred with that of Rhind (1987)
who concluded that many people were unable to distinguish stiffness from the
sensation of pain. This study however has been the first to consider how people with
differing knee status understand stiffness. The study by Rhind (1987) was undertaken
on those with rheumatoid arthritis only and focussed on metacarpophalangeal joint
stiffness. There has been no previous work which has explored the perceptions of
knee joint stiffness in those with OA yet stiffness is considered to be a diagnostic
indicator for OA (Manek & Lane, 2000). In the current study participants in the OA
group were more likely to use words from the pain category than those in either the
TKA or control groups. These results tended to agree with those by Gooberman-Hill
et al (2009) who used qualitative methods to study patients’ experiences with OA
and concluded that stiffness described the relationship between changes in joint
position and pain. The purpose of the study by Gooberman-Hill et al (2009) however
was to compare patient experiences of hip and knee OA with respect to pain and
limitations rather than to consider how patients experience stiffness. Stiffness was
therefore explored with a focus on pain and thus it was not perhaps surprising that
pain and stiffness were found to be linked. In the current study, the OA group
comprised of those who were due to undergo TKA for OA and therefore unsurprisingly reported high levels of knee pain. The OA group reported significant higher pain than either the TKA or control groups and the number of participants in the OA group who used words from the pain category to describe their stiffness was significantly higher than the TKA or control groups. These results suggested that a relationship between pain and self-perceived stiffness may exist and further work is required to explore how pain influences perceptions of stiffness.

Although pain was frequently used to describe stiffness, 65% of the words selected to describe stiffness came from the categories of ‘difficulty with movement’ and ‘sensations’. Furthermore, words from the pain category were only used exclusively by 8% of participants. Forty percent of participants circled words from more than one category. All combinations of categories were used with the exception of ‘sensation’ alone and nearly a fifth chose words from all 3 categories. These results suggested that perceptions of stiffness were unique to individual patients and that understanding of the term ‘stiffness’ was varied.

Although the results from the patient perceptions of the severity of stiffness tended to support the evidence for stiffness as a diagnostic criterion for OA, the results of the descriptors of stiffness suggested that self-reported stiffness scores such as the VAS or WOMAC may not necessarily be valid measures of true stiffness. The suggestion that patients were unable to distinguish sensations of stiffness was further corroborated by the lack of a statistically significant relationship between subjective and objective measures of stiffness. Self-reported sensations of higher stiffness were not associated with higher measures of objective stiffness or increased stiffness earlier in range. This is the first study to have considered the validity of self-reported
stiffness by using an objective measure of stiffness. Although the sample size was small, casting doubt on the robustness of the conclusions of the correlation analysis, together with the evidence from the descriptors of stiffness, these results call into question the validity of self-reported measures of stiffness.

In addition to differences found between groups in the WOMAC scores, differences were also found between the OA group and TKA/control groups in the SF-12 Physical Component Summary (PCS). On average all groups showed lower scores than the population average (US data). Mizner, Petterson, & Snyder-Mackler (2005) provided a summary of previously reported PCS scores at pre-op which ranged from 25.9 – 34.3. The mean score of 35.5 in the OA group was comparable to these values. At 1 year post-op the current study found the PCS score of 43.6 also to be comparable with other studies (Bert, Gross, & Kline, 2000). Again there was little data on healthy age matched controls and in particular, healthy UK based control populations. In the current study, all groups demonstrated a mean PCS score that was below the US population average. The problem with using the US population average was that it was a) US based and b) not age adjusted. There is evidence to show that physical functioning measured by the SF-36 (a longer version of the SF-12) declines with age (Hemingway et al., 1997).

In contrast the average mental health scores showed no differences between groups and the overall average of 51.5 was just above the US population average. This may be explained by the fact that mental health has actually been shown to improve with age (Hemingway et al, 1997).
8.3.2 Performance based measures of function

As expected, the OA group showed significantly slower TUG times and walking speed than either the TKA or control groups. However, performance based measures of function also reflected the patient reported outcomes in that they indicated no significant difference in functional limitations in the TKA group compared to the control group. There are only a few studies who have reported such timed scores at 1 year post TKA and there is little agreement amongst those who have. Some studies found significant differences between TKA patients in walking speed (Walsh et al, 1998), stair ascent times (Farquhar, Reisman, & Snyder-Mackler, 2008; Walsh et al, 1998) and TUG (Boonstra, De Waal Malefiet, & Verdonschot, 2008; Rossi et al, 2006) at 1 year post-op compared with controls. Others however have reported no difference in walking speed or stair ascent/descent (Yoshida et al, 2008) nor the TUG (Farquhar, Reisman, & Snyder-Mackler, 2008; Yoshida et al, 2008). Compared to Walsh et al (1998) TKA patients in the current study walked faster and the control subjects walked slower which may explain why Walsh found a difference where the current study found none. Yoshida et al (2008) reported faster walking speeds for both TKA and control however the participants in the study were younger than in the current study which is likely to have influenced the results. Different protocols have been applied for the assessment of walking speed which may also have influenced the findings. For example Walsh et al. (1998) established speed over 160 m involving 8 laps of a 20 m course and Yoshida et al. (2008) used a 6 min walk test whereas the current study used a 13 m walk test. There has been no work to assess the comparability of these tests in an orthopaedic population and thus differences could be attributed to methodological differences. Kirtley (2006) provided normative
values of indoor walking speed of 1.3 to 1.6 m/s for men and 1.2 to 1.5 for women. These values were not adjusted for age however but they indicated that the values for the control and TKA groups in the current study were at the lower end of normal. Kirtley (2006) also noted that a person's normal gait is dependent on the environment and that subjects walk faster on longer walkways. They also tended to walk faster outdoors than indoors.

Although not strictly a measure of function, leg extensor power is a measure of quadriceps strength which has been shown to correlate strongly with performance based measures of function (Yoshida et al, 2008). The current study found no significant differences in knee extensor strength as measured by leg extensor power between the groups although unsurprisingly, differences between genders existed. Thus the lack of significant difference in leg extensor power may have contributed to the lack of significant difference in the other performance based measures of function. The normalised leg extensor power values were however lower than those previously reported (Frost, Lamb, & Robertson, 2002). Previous studies have shown that the operated knee has significantly less quadriceps strength than the unaffected knee both pre-operatively and in the early post-operative period (Farquhar, Reisman, & Snyder-Mackler, 2008; Mizner, Petterson, & Snyder-Mackler, 2005). Both these studies however assessed strength using a Maximal Voluntary Isometric Contraction (MVIC) which only assesses muscle strength at one point in range. The leg extensor power analyser measures maximal quadriceps strength throughout range and may therefore represent maximal quadriceps strength better than an MVIC. These methodological differences between the current study and previous work combined
with differences in the post-operative reporting period, explain why the results of the current study disagreed with those previously reported.

8.4 Joint stiffness

To the author’s knowledge, this was the first study to attempt to quantify knee joint stiffness following TKA (other than by the WOMAC stiffness component). It was also the first to have considered the influence of knee joint stiffness upon functional ability following TKA. There are no previous studies of objective measures of stiffness in TKA with which to compare results although a very small number of studies have considered stiffness in the OA knee joint and these will be discussed.

8.4.1 Stiffness values

The results showed that although raw stiffness values for the TKA group were generally highest and the OA values lowest, these differences were not statistically significant. Similar trends were found when the data was normalised to thigh circumference. Medium effect sizes (Cohen, 1992) were seen in stiffness values (both raw and normalised) at the slow velocity although no statistically significant differences were found. It is acknowledged that the sample size was small and therefore it was likely that the study was underpowered i.e. it lacked the strength to detect differences should they exist. The post-hoc analysis presented in section 7.10 indicated that a sample size of 164 would have been necessary to provide adequate power to detect inter-group differences in stiffness. The current study achieved a recruitment rate of around 33% of all those approached. Thus a population of around 492 would have been required in order to recruit sufficient numbers. These estimations were based on mean values and as the datasets were not normally
distributed, they may not have been accurate however they serve as a rough estimate of sample sizes needed for statistical significance. Sexton et al. (2008) noted that there are a number of factors which can influence the power of a study, other than manipulation of the alpha level (which may have undesirable consequences on the risk of a type I error) and increasing the sample size. They included; increasing the sample size of the control group, reducing the standard deviation of the measurement, increasing the size of the effect and reducing the number of experimental groups. Reducing the standard deviation would have increased the effect size without the necessity to have increased the size of the difference between the groups. Higher effect sizes would have resulted in better power. The results of this study showed large inter-individual differences in stiffness which may have contributed to the lack of power. Large variances however have been noted in other studies (Heerkens, 1985; McFaull & Lamontagne, 1998) and thus large variances may accurately reflect the nature of stiffness in the general population.

When stiffness variables were normalised to thigh mass, differences remained statistically non-significant. Effect sizes were reduced although normalised slow flexion stiffness still showed a moderate effect size. As thigh mass was not significantly different between groups, it was perhaps not surprising that normalisation to this variable did not result in differences in stiffness values. Heerkens (1985) found that thigh circumference (a potential predictor of thigh mass) was a significant influence on stiffness variables however this was primarily due to gender differences. Similarly Blackburn et al (2004b) found gender differences in knee extension stiffness which were attributed to differences in mass and height. As there were significant differences in the male:female ratio within the groups in the
current study, it was important to consider whether gender was a significant influencer on stiffness outcomes. In the current study no significant differences in stiffness between genders was identified although the sample sizes were admittedly small. Although there were differences in the proportion of genders, there were no differences between groups or genders in terms of weight or BMI (there were differences in height). There was no estimation however of the thigh muscle mass and it is possible that although there were no differences in thigh circumference, there may have been differences in the quadriceps muscle mass which may have influenced the results. Women are known to store fat around the gluteal-femoral region whereas men tend to have more fat in the abdominal area (Blaak, 2001). Thus, although there were no significant differences between genders in thigh circumference, it is likely that the muscle mass in the thigh was less in the females than the males. Furthermore, the previously described studies that have ascribed gender differences in stiffness to differences in height and weight have been undertaken on much younger populations with a BMI in the ‘normal’ band (18.5 – 24.99) (World Health Organisation, 2009) whereas the participants in the current study had a mean BMI of 29.04 (95% CI 28.09 – 30.99) which is classified by the WHO as overweight (pre-obese).

It was difficult to compare values found in the current study with previous literature due to variability in the way that stiffness has been previously reported. Few studies have reported stiffness according to the definition within Physics (Latash & Zatsiorsky, 1993). Earlier studies reported the passive resistive moment (Heerkens, 1985; Mansour & Audu, 1986; McFaull & Lamontagne, 1998; Such et al, 1975) however this has been shown to be strongly influenced by anthropometric parameters
(and therefore by gender). Furthermore, several studies have shown gender differences (Blackburn et al, 2004b; Heerkens, 1985; Such et al, 1975) in knee joint stiffness although in the latter two studies this was in younger, healthy subjects. Such et al (1975) reported gender differences but these differences appeared to reduce with age. Furthermore, as others (Mansour & Audu, 1986; McFaull & Lamontagne, 1998) have pointed out, biceps femoris, semimembranosus and semitendinosus are biarticular, crossing both the hip and knee joints. Variance in hip and knee angles will cause differences in the passive extension stiffness of the knee and therefore must be taken into account when comparing studies. Similarly, rectus femoris and sartorius will influence the passive flexion stiffness of the knee. In the current study, the ankle was fixed at neutral and the hip at 70° flexion.

One study ((Blackburn et al, 2004b) that has reported stiffness values in a similar way to the current study only reported the passive stiffness of the knee flexors and reported the stiffness as Nm/rad. It was decided in the current study to report the data as Nm/deg as the knee angle measurement in degrees was more clinically relevant. The mean value reported by Blackburn et al (2004) for males was 12.66 Nm/rad which converted to 0.221 Nm/degree and 8.45 Nm/rad for females which converted to 0.147 Nm/degree. These values were lower but not dissimilar to the value of 0.343 found in the current study control group, for slow extension stiffness. The population however was not comparable with the current study as Blackburn et al (2004) reported on a young healthy population but the data agreed with the assumption that stiffness may increase with age. It is also worth noting that Blackburn et al (2004) used a hip angle of only 30° flexion and did not state the ankle angle. Smaller hip
angles will result in lower stiffness values for the knee flexors in the final degrees of knee extension due to the two-joint nature of the hamstrings muscles.

Two previous studies (Oatis et al, 1995; Zeni & Higginson, 2009) have considered stiffness in the OA knee. Both studies report increased stiffness in the OA knee compared with healthy controls however comparison with the current study was difficult. Oatis, Wolff and Lennon (2006) used a simple pendulum test which was only able to determine stiffness at particular preset angles. Although Zeni & Higginson (2009) reported differences in stiffness those with severe knee OA compared to those who were asymptomatic, only dynamic stiffness during the loading response of gait was determined. This limited the stiffness calculations to the first 25° of flexion. The current study explored flexion stiffness as the knee approached full flexion. Although extension stiffness was determined to take place as the knee extended from around 30° of flexion to 0°, this was as the knee extended. The direction of the movement has been shown to influence the calculated joint stiffness and this may account for differences between the current study and Zeni & Higginson (2009). Zeni & Higginson (2009) however did hypothesise that those with knee OA may demonstrate higher muscle activity by the antagonist muscles (and thus higher joint stiffness) in order to counter the instability and joint laxity that has been reported in OA knees. If this hypothesis were to be true, then during passive activity (where there is no antagonistic muscle activity and joint instability and laxity are uncontrolled), lower stiffness values might be expected in the OA knee compared to controls. The results of the current study suggested that flexion stiffness might be lower in the OA group but these results were not statistically significant. This trend was in agreement with other studies that have found decreased stiffness in patients
with RA (Helliwell, Howe, & Wright, 1988). In contrast, a small study (Valle et al., 2006), using similar methods to that of Oatis et al. (1995), also reported higher knee joint stiffness in women with rheumatoid arthritis (1.91 Nm/rad) compared with controls (1.32 Nm/rad). The amplitude of knee flexion during the pendulum test was also reduced in the RA group. It was difficult to compare results of studies that have used the pendulum test to report stiffness, to data from the current study. In the pendulum test, stiffness is calculated from the damping coefficient and is not angle specific. This study showed that the rate of change of resistive torque differs depending on the point in range that stiffness is measured. Early work by Wright & Johns (1961) on metacarpophalangeal joint stiffness also found increased stiffness in those with RA although this early work does not actually present any statistical evidence for the claims. It has been suggested that joint stiffness potentially results from a combination of sources that may include ligaments, tendons, cartilages, the joint capsule, muscles and bones (Helliwell, Smeathers, & Wright, 1994; Latash & Zatsiorsky, 1993). Johns & Wright (1962) suggested that tendons accounted for stiffness at the end of range whilst midrange stiffness was provided by the joint capsule and muscles. Helliwell, Howe, & Wright (1988) attributed reduced stiffness in RA to the pathology of the disease process. They explained that the inflammatory process leads to distortion and distension of the joint capsule and its surrounding structures. Together with muscle weakness, this leads to reduced joint stiffness. Although the pathological basis of the explanation in rheumatoid arthritis was different to that offered for OA (Zeni & Higginson, 2009), the result of the pathology is similar – joint laxity and instability which could lead to reduced passive joint stiffness.
Although no significant differences were found, there was a trend to higher stiffness in the prosthetic knee, compared to the control knees. Stiffness in the prosthetic knee could have arisen from a number of sources including: position of the joint line, size of the polyethylene insert, peri-operative soft tissue balancing,

Previous studies (Mansour & Audu, 1986) have observed hysteresis loops in torque angle curves providing evidence that stiffness depends on the direction of joint motion.

8.4.2 Stiffness threshold angles

Significant differences were observed between groups in the stiffness threshold angles. The control group demonstrated significantly greater flexion (110° compared to 90°-95° in the OA/TKA groups), before stiffness was observed to increase. There were no differences between the TKA and OA groups. Interestingly, they demonstrated less extension before stiffness in extension was observed.

There has been no previous work to explore the stiffness threshold angle neither in this age group nor in subjects with knee OA or TKA. The stiffness threshold angles were however lower than those previously reported in a small groups of young male subjects (McFaul & Lamontagne, 1993; Riener & Edrich, 1999). Although neither study actually reported the stiffness threshold angle, the values could be estimated from the graphs of knee joint moment vs knee angle. Both studies reported that knee flexion stiffness appeared to increase significantly at around 130° of flexion and around 12° from full extension. These results indicated that the mid-range of motion, where stiffness was seen to be negligible, had a wider range in younger healthy males than in the current study population.
When data was normalised to maximum active flexion, there were no significant
differences between groups. The data suggested that the stiffness threshold angle
occurred at around 80%-90% of full flexion, regardless of the amount of flexion
available. The significant differences seen in the raw data were likely to have
occurred as a result of inter-group differences in maximum passive knee flexion.
Latash & Zatsiorsky (1993) suggested that the stretch reflex mechanism caused an
involuntary activation of the stretched muscle as the joints neared its limit of range of
motion and the joint could no longer be considered to be passive. Hagood et al
(1990) found the stretch reflex to be correlated with the limb velocity although these
findings were not supported by later work (McNair et al, 2002). In the current study,
EMG activity of the quadriceps was monitored and any trials which demonstrated
activity above 3.5µV were discarded. Thus, if during knee flexion, a stretch reflex in
quadriceps had been elicited, increased activity would have been noted and the trial
discarded. Very few trials were discarded for this reason, supporting the theory that
the stretch reflex was not a plausible explanation for the increase in stiffness
observed at around 80% of the joint range. The current study found no difference in
the stiffness threshold angle or torque between fast and slow velocities. Previous
studies have only undertaken stiffness measures at very slow velocities which
removes the need to account for inertia of the system and leg. However the
viscoelastic property of human tissues meant that there may have been differing
responses at the joint to passive motion at slow and fast velocities. Human tissues
such as muscle and tendon have been shown to be stiffer when subjected to faster
strain rates (Fung, 1993; Panjabi & White, 2001) and therefore it was expected that
knee joint stiffness would be greater at the faster velocity. This was a potentially
important factor to explore since most functional activities are not performed with
the slow angular rotations at the joint seen in the previous studies of stiffness.
Significant differences were seen in extension stiffness between the fast and slow
velocities. The seated position of the participants meant that the hamstrings muscles
were already under some degree of tension. It may have been possible that the
stretch reflex of the hamstrings group was elicited particularly during knee extension
at the faster velocity.

The fact that normalised values were similar between groups suggested that the
tissues responsible for the increase in stiffness were extra-articular. Knee flexion is
normally limited primarily by apposition of the posterior soft tissues and tension of
the quadriceps muscle. Extension however is limited primarily by the ligaments:
anterior and posterior cruciate, medial and lateral collateral, the posterior joint
capsule and the oblique popliteal ligament as well the length of the hamstrings
(Moore & Agur, 2007). Normal knee flexion is considered to range of 0° extension to
120°-140° flexion (Lehmkuhl & Smith, 1983). Flexion stiffness was observed to
increase significantly at around 80% of full flexion suggesting the apposition of the
soft tissues was not a likely cause of the increase in resistance to passive motion.
Therefore, the most likely explanation for the increase in resistance to passive motion
was tension in the quadriceps muscle. As stiffness was seen to increase at around
80% of full flexion, regardless of the amount of flexion, this suggested that adaptive
shortening of the quadriceps could have taken place in the OA and TKA groups. A
study of range of movement utilised during functional activities post-TKA (Myles et
al, 2001) showed that patients with TKA only tended to use around 80% of available
active knee flexion during activities such as stair ascent/descent, in/out of a chair,
in/out of a bath. The maximum knee flexion used was significantly less than that employed by an age matched healthy normal control group. However the TKA population also had significantly less active knee flexion than the control group. When the maximum knee flexion during functional activities was considered as a percentage of the maximum knee flexion, the differences between the two groups was reduced. The control group used approximately 70-80% of maximum active flexion compared to around 80% in the TKA population. In the current study, flexion stiffness increased significantly at around 80% of knee flexion which could explain why patients in Myles et al (2001) study were unable to utilise a greater range of movement during functional activities.

Esteki & Mansour (1996) noted that the elastic component of the passive resistance to motion was dependent on the static equilibrium position of a joint. Neutral position for the knee was reported to be about 133° flexion (Latash & Zatsiorsky, 1993) although this was altered when the hip angle was altered. The following formula has been recommended for the calculation of the knee neutral angle: knee neutral = 60.4 + 0.57β where β is the hip angle (Latash & Zatsiorsky, 1993). In the current study, the hip was flexed to 70°, giving a knee neutral position of 103° flexion. Passive joint stiffness values are low around the neutral joint position.

8.4.3 Stiffness threshold torque values

In addition to actual stiffness values, the passive resistive torque was also measured. There were differences between studies in the reference point for this torque. In the current study, the point at which the stiffness was seen to increase significantly was taken and defined as the stiffness threshold torque. Others have determined the
passive resistive torque at predefined angles (for example, McFaull and Lamontagne (1998) measured the torque at 140° of flexion). Some studies (Heerkens, 1985; Such et al, 1975), notably older studies, failed to provide this information. The decision was taken to compare the stiffness threshold torque in the current study rather than at predefined angles. It was assumed that not all subjects would be able to achieve the same range of motion due to pain, flexion contractures, stiffness etc and therefore the point of threshold stiffness provided a suitable reference point.

The stiffness threshold torque provided additional information to the stiffness and threshold stiffness angle values. Stiffness has been defined as the change in torque per unit of displacement. It was possible that stiffness of different participants could have been similar whilst the actual resistive torque values were different.

The results showed that there was no statistically significant difference between the groups. In all variables, the trend was for the OA group to have the smallest resistive torque values. These results were surprising as it was expected that participants in the OA group would demonstrate higher resistive torque. However, the lower resistive torque was consistent with the decreased stiffness in OA subjects, discussed in section 8.4.1 and potentially explained by the joint laxity and instability often observed in OA knees. Although the sample size was adequate to detect between group differences in other variables, the lack of statistically significant differences may have been due to lack of sensitivity in the measurement tool. Large variances were observed in the torque values which reduced the ability of the tool to detect small differences. A larger sample size would be required to confirm whether differences exist or not in this variable.
8.5 Relationship between stiffness measures and function

In order to determine whether stiffness was associated with functional limitations, correlational analysis was undertaken. As has been suggested in section 8.3.1., osteoarthritic knees may demonstrate instability and joint laxity. Replaced knees can also demonstrate instability in mid-range or stiffness in flexion.

8.5.1 Patient reported measures of stiffness and function

Patient reported stiffness (VAS) showed a moderate correlation with WOMAC function however associations with WOMAC stiffness and function were strong. Low associations (rho = 0.4 – 0.5) and large effect sizes were seen between patient reported stiffness (VAS) and the TUG, the stair ascent/descent and walking speed. Similar associations were seen between the WOMAC stiffness scores and the measures of function. Lower stiffness scores (less stiffness) were associated with lower WOMAC function scores (less functional limitations) and higher PCS scores (better function). Lower stiffness scores (less stiffness) were also associated with smaller TUG times (faster speed), smaller stair ascent/descent times (faster speed) and larger walking speed (faster speed). These results supported the hypothesis that patient perceptions of stiffness may be associated with functional ability. Relationships were seen between patient reported stiffness and both patient reported and performance based measures of function, strengthening the case for function being affected by perceptions of stiffness.

Few studies have considered the relationship between stiffness and function. One study reported the correlation between WOMAC scores and function at 1 year post-TKA (Witvrouw et al, 2002) however the lack of detail in the methodology made it
difficult to make comparisons. The methods failed to state how the WOMAC was scored (VAS or Likert, worst-to-best or best-worst) however the post-TKA function scores at 1 year were 8.3 suggesting that the scores were best-to-worst (consistent with the original scoring system) and, assuming this, were better than the function scores reported in the current study. The study used the Dynaport test (van den Dikkenberg et al, 2002) which uses accelerometers to measure function during a range of activities of daily living. Although not widely used in outcome studies, the Dynaport test has been thoroughly tested for validity and reliability (Mokkink et al, 2005). The results of correlational analysis of the Dynaport test with WOMAC showed only low levels of association between function and stiffness ($r = 0.216$) but no indication was given of the associated $p$-value. These results did not agree with other studies (Finch et al, 1998) who found moderate correlations ($r = -0.51$ to -0.64) between stiffness and walk speed and stair performance. Interestingly, correlations were only found in male participants and no relationship was seen between stiffness and stair climbing ability in TKA subjects, only male controls. Low but significant associations have also been seen between patient reported stiffness and walk speed, TUG and stair ascent/descent tests in those awaiting hip replacement (Mori, Lundon, & Kreder, 2005).

The associations between self-reported stiffness and function found in the current study concur with previous work (Maly, Costigan, & Olney, 2006) which found that self-reported perceptions of stiffness (WOMAC) were a significant predictor of the confidence with which individuals with OA undertook their daily activities (assessed with the Functional Self-Efficacy Scale). Muscle strength, age and mental health were the only other contributors. Maly, Costigan and Olney (2006) hypothesised that
perceptions of increased stiffness provided negative feedback to individuals which resulted in worse confidence in their ability for physical tasks. Self-efficacy has been shown to be strongly associated with self-reported functional ability (Harrison, 2004) and therefore it was possible that negative feedback as a result of increased perceptions of stiffness could explain the worse self-reported function found in the current study. Maly, Costigan and Olney (2006) concluded by recommending that further work be undertaken to characterise stiffness at the knee joint and added that the relationship between mechanical stiffness and mobility should be considered as well the relationship between perceived stiffness and mechanical stiffness. These previously described studies however were only undertaken on individuals with knee OA. These participants were not considered as having end-stage OA (i.e. not listed for TKA) and therefore these results may not be generalisable to those either awaiting TKA or those who have had TKA. A review of the literature found no similar work on a TKA population.

Self reported pain and function has already been shown to be strongly correlated (Kennedy et al, 2003; Stratford & Kennedy, 2004). The results from the current study which showed that patients’ ability to distinguish between perceptions of pain and stiffness was poor, could explain the relationship between self reported stiffness and self-reported function. However the evidence that performance based measures of function were also associated with self-reported stiffness strengthened the argument that patient perceptions of stiffness and function were related.
8.5.2 Objective measures of stiffness and function

Although not significant, normalised measures of flexion stiffness showed some suggestion of association with measures of function. Correlation coefficients of around 0.3 (low association) were seen between normalised slow flexion stiffness and WOMAC function, TUG, stair ascent/descent and normalised leg extensor power. The nature of the relationship was negative between stiffness and WOMAC function, TUG and stair ascent/descent indicating that lower stiffness was associated with more functional limitations, slower TUG times and slower stair ascent/descent. The relationship with normalised leg extensor power was positive indicating that less stiffness was associated with weaker quadriceps strength. The nature of these relationships can be accounted for as follows: although sit-stand and stair ascent/descent require a greater range of motion than walking (Jevsevar et al, 1993) and therefore increased ability in these activities might be thought to be associated with increased range of motion, they also require stability at the knee joint whilst the knee is being loaded (Andriacchi, Galante, & Fermier, 1982). Less stiffness could have been associated with knee joint laxity and feelings of instability, which in turn could have resulted in patients reporting more functional difficulties and slower times. This study has been the first to study the association between objective measures of stiffness and function and further work is necessary to explore whether less stiffness is associated with knee joint instability during joint loading.

Oatis, Wolff and Lennon (2006) found a significant correlation between the knee damping coefficient and the WOMAC stiffness sub-score but no relationship could be found between objective measures of stiffness and function. The sample size used by Oatis, Wolff and Lennon (2006) however was also small (n = 9) and the
limitations of the pendulum method, previously discussed, mean that the results must be viewed with caution.

Although the p-values for the correlation coefficients between normalised slow flexion stiffness and measures of function were not significant, they were observed to lie just outside the alpha level. Large effect sizes were observed and therefore it may be the case that the small sample size may have resulted in the analysis being underpowered.

8.5.3 Threshold stiffness angles and function

If the theory postulated in section 8.4.2 that patients used a lower range of motion during functional activities because of stiffness, was true, it would follow that lower threshold stiffness angles would have been associated with increased difficulty with function. This would be particularly true for the activities that required a higher range of flexion, such as the TUG and the stair ascent/descent test. No previous studies however have considered the impact of the threshold stiffness angle on functional ability.

The tests of relationships between threshold stiffness angles and function showed that only the leg extensor power had any significant association. Positive correlation coefficients were seen between both slow and fast flexion threshold stiffness angles and the leg extensor power which suggested that higher flexion stiffness threshold angles were associated with stronger leg extensors. As the flexion stiffness threshold angles were seen to be a function of maximum available knee flexion, it was likely that the higher leg extensor power values were associated with better knee flexion. This would agree with previous hypotheses which have postulated that better
quadriceps strength was associated with increased knee flexion excursion during gait (Mizner, Petterson, & Snyder-Mackler, 2005; Yoshida et al, 2008). It seemed unlikely that the relationship is causal (and indeed this cannot be concluded from the results of the current study) but previous studies (Mizner, Petterson, & Snyder-Mackler, 2005) have indicated that improvements in both strength and ROM were necessary for good outcomes and may go some way to explain why those who had higher flexion also had better strength. Better flexion may have also influenced leg extensor power as follows: Leg extensor power was calculated from the power generated through the extension of the knee (reported as Watts). Power is usually calculated as the rate at which Work is done (Griffiths, 2006), where work is calculated by the following equation

\[ \text{work} = \text{force} \times \text{distance} \]

Where distance is the distance the object moves in the direction of the applied force. Thus the power was potentially influenced by; 1) the maximum force the knee extensors were able to produce, 2) the distance that the footplate of the Leg Extensor Power Analyser could move and 3) maximum velocity of knee extension that the knee extensors were able to generate. Greater flexion thus provided an opportunity to increase the distance the footplate moved and therefore may have influenced the maximum leg extensor power that could be generated.

The normalised fast flexion stiffness threshold angle was shown to be significantly correlated with TUG, stair ascent/descent and walking speed however positive correlations were seen with the TUG and stair tests, and negative for walking speed. The sign of these relationships indicated that a greater flexion stiffness threshold (as a percentage of total passive flexion) was associated with longer times taken to

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249
complete the TUG and stair tests. In addition a greater flexion stiffness threshold (as a percentage of maximum passive flexion) was associated with a reduced gait speed (slower m/s). The reasons for this were not entirely clear. Reduced stiffness earlier in range may have also been associated with feelings of joint laxity and instability resulting in participants being more cautious about knee loading during sit-stand, walking and stair climbing. No such associations were seen between the actual threshold stiffness angles and the TUG, the stair test and walking speed indicating that the value of the absolute threshold stiffness angle does not necessarily influence the association.

Interestingly patient reported measures of function were not significantly correlated with the threshold stiffness angles, giving further strength to the evidence that patient perceptions of function were influenced by other factors.

It was not expected that there would be any significant relationship between extension threshold angles and function. The functional activities tested did not require the participant to challenge their knee in the final degrees of extension and therefore stiffness in this range would be unlikely to influence ability to carry out these activities.

8.6 Limitations and sources of error

The study contains a number of limitations which affected the ability to generalise the results. Furthermore, the potential impact of sources of error on the reliability of the results must be considered.
8.6.1 Limitations

The small sample size, particularly in part 1 of the study, resulted in the study being underpowered to detect inter-group differences in objective stiffness measures or to identify significant associations between variables. Recruitment was lower than anticipated with only a 33% response rate. In addition, the outcomes data for the TKA group suggested that the cohort was a particularly high functioning sample and it is likely that it was not representative of the wider TKA population. Therefore the study was limited in the generalisations that could be made.

The proportion of the genders within each of the groups was discussed in section 8.1. The gender proportions of the TKA and OA groups did not reflect the general TKA population. Although gender has been shown not to influence outcomes (Ritter et al., 2008b), stiffness variables (as discussed) may be subject to inter-gender differences. Although this study overall found no gender differences, there may be some limitations to the applicability of the results to the wider TKA population.

Function was measured using self-report (WOMAC and PCS) and performance based measures. This approach was recommended by several previous authors and the measures used were considered as valid and reliable. The WOMAC scores however showed scores that were very near the minimum, particularly for the control group. Thus a ceiling (floor) effect may have been present, particularly with respect to function. The WOMAC has been shown previously to be subject to ceiling (floor) effects (Marx et al., 2005) and thus it may be limited in its ability to detect functional limitations in high functioning individuals. The performance based measures also showed no significant difference between TKA and control patients. This may be a
result of a lack of sensitivity in the measures. Several studies (Parent & Moffat, 2002; Stratford & Kennedy, 2006) have recommended including performance based measures alongside patient reported measures in the evaluation of function following TKA; however these recommendations were based upon the evaluation of responsiveness to change between pre- and post TK surgery. In the early stages of recovery, simple tests may be sufficient to detect improvements in function. None of the simple tests of function utilised in the current study could have accounted for limitations in more complex activities such as gardening and other activities involving squatting and kneeling. One study (Weiss et al, 2002) found that up to 75% of patients reported functional limitations when questions about these more challenging activities were posed. It would appear that, in general, day-to-day activities such as walking, stair climbing and chair transfers did not present significant problems for patients with TKA however the study was limited in the conclusions that could be made with regards to higher level functional activities.

As rectus femoris crosses both the hip and the knee (Moore & Agur, 2007), maximum tension in rectus femoris is developed only when the hip is extended and the knee is flexed. In this study, objective knee joint stiffness was assessed with the hip in 70° of flexion. It is possible that knee flexion stiffness was underestimated in relation to knee joint stiffness during activities where the hip in extension i.e. during mid-stance and terminal stance phases of gait.

8.6.2 Sources of error

As with any study where decisions are based on probability, where no significant differences or relationship were observed, there was a risk of Type II error (so called
‘missed’ findings). Type II errors occur where studies lack the power to detect differences. Lack of power can result from a number of issues; the alpha level, the magnitude of the differences, the variability of the samples and the sample size (Vincent, 2005). The magnitude of the differences and the variability of the samples were potentially subject to influence from error arising from the instrumentation, participants or the researcher. The potential for error from each of these sources will be considered.

Error from instrumentation in this study arose mainly from the stiffness measurement rig. Pilot studies on the stiffness rig (reported in section 5.5) showed good reliability and validity for stiffness measures. A check of the reliability of the participant data however showed that there was some intra-trial variance and that extension stiffness at the faster speed in particular showed only fair-moderate reliability. This suggested that the some of the objective measures of stiffness lacked sensitivity. Standard error of measurement was calculated from 3 trials taken from each participant using the calculations provided by Stratford (2004). Stiffness measures were found have a measurement error of 0.167 – 0.930 Nm/deg with fair to moderate reliability. Taking the magnitude of the actual values into account, the largest error of 0.93 Nm/deg (for fast extension stiffness) was larger than the actual values for either the control or OA groups. These results indicated that the stiffness rig was not sensitive enough to detect inter-group differences in actual stiffness. It is likely that this error contributed to the lack of statistically significant differences in stiffness. Threshold stiffness angles were found to have a measurement error of 0.689° – 2.857° with excellent reliability and significant differences were found in stiffness threshold angles for flexion at both fast and slow speed. These variables showed measurement error of
1.9° (fast velocity) and 0.7° (slow velocity). In the context of the actual values (90° – 110°) the magnitude of the measurement error was small. The largest error (2.857°) was for the threshold stiffness angle during the extension phase at fast velocity. The actual values for this variable ranged from 16° – 31°. Although the magnitude of the measurement error in relation to the actual values was larger for the extension angles, they were still small compared to those for stiffness. Overall the measurement error for the threshold stiffness angle variables suggested that the stiffness was rig was sufficiently sensitive to detect differences in threshold stiffness angles. Threshold stiffness torque values were found to have a measurement error of -.4 - 1.3 Nm. The largest error (1.3 Nm) was for threshold stiffness torque during the flexion phase at fast velocity. The actual values for this variable were around 3Nm. The values indicated that the measurement error for threshold stiffness torque was large compared to actual values and suggested that the rig was not sufficiently sensitive enough to detect inter-group differences.

The rationale for introducing tests at the faster velocity was to look at stiffness in a joint undergoing a rotation at a velocity similar to that experienced during functional movements. Inertia was corrected for using estimations of the mass moment of inertia of the leg obtained from anthropometric data. Inertia of the system was estimated using data obtained from the unweighted rig and using curve fitting to predict the torque at a given angle. Following the correction, it was observed in some of the data that the resulting passive resistive moment appeared to be aiding the direction motion rather than acting against the movement. This would occur when the torque applied to the rig handle was attempting to slow the movement down rather than sustain movement. This suggests that there were some inaccuracies in
some of the estimated data which were used to in the biomechanical model. Anthropometric data was generalised from tables based upon participant weight/height and may have been inaccurate if the mass distribution of the participants was different than the subjects on which the anthropometric tables were based. This was more likely to have occurred where participants were overweight. The distribution of adipose tissue may not be even and thus the estimation of leg mass from the total body mass may be subject to error. Further error may have been introduced through estimation of the inertial components in the biomechanical mode. Calculation of the angular acceleration of the segment was achieved by using the second derivative of the displacement data obtained from the electrogoniometer. As Stergiou (2004) noted, the differentiation process can cause the noise in the signal to be amplified to a level where the noise becomes the more significant part of the signal. Thus appropriate filtering was necessary. In this study a fourth order Butterworth filter was applied which is the most commonly use filter in human movement studies (Winter & Patla, 1997). However, even with appropriate filtering it was possible that noise in the signal caused errors in the estimation of the angular acceleration data and thus the inertia. Even though inertia was corrected for, some of the fast values torque values showed directions in the opposite direction than expected. The velocity of the slow trials was slow enough not to have been affected by inertial components.

Measurement of the resistive torque assumed that the centre of rotation of the stiffness rig remained aligned with the centre of rotation of the knee. The centre of rotation of the knee could only be estimated from surface markings of the knee, normally accepted to be the lateral femoral epicondyle. Movement of the surface
markings relative to the bone in motion studies has been acknowledged as a source of error (Leardini, 2005). This was minimised in the current study by isolating the movement to a single joint and by applying appropriate data filtering. Furthermore, in those patients who had significant adipose tissues around the knee joint, alignment was more difficult to ensure.

Participants introduce a potential source of error. Participants were made aware of the purpose of the study and therefore there may have been some potential for participants to alter their responses (Field & Hole, 2003), in particular to the questionnaires, as a result. The TKA group in particular may also have been (consciously or unconsciously) influenced by their experiences of surgery and hospital stay. Although there is little evidence to suggest these experiences influence likelihood of volunteering, all the participants in the TKA anecdotally reported highly positive hospital experiences and reported feeling grateful for the opportunity of ‘giving something back’. A further source of participant error may have arisen from the passive nature of the objective stiffness measures. Participants were required to remain passive whilst the limb was flexed and extended. Electrical activity of the quadriceps muscle was monitored using EMG and if participants were unable to relax sufficiently during the test, the trial was discarded. One participant was unable to relax sufficiently at all and no data for objective stiffness was recorded. Only EMG activity in quadriceps was monitored and this may have resulted in some trials not being discarded as there could have been hamstrings activity which had gone undetected.

Experimenter bias has been well documented (Field & Hole, 2003) and the lack of blinding of the researcher may have influenced the analysis of the results. All effort
was made to interact with study participants in the same way but it is possible that unconsciously, the researcher influenced participants to respond differently.

One final potential error arises from the non-weight bearing, passive nature of the objective stiffness measurements. Joint stiffness during activities of daily living arises, in part, from antagonistic muscle activity. Zeni & Higginson (2009) discussed the contribution of such muscle activity to increased joint stiffness, proposing that higher muscle activity was required to reduce the pain associated with movement in those with knee OA. Thus the joint stiffness observed in the current study may be less than that experienced by those with knee pathology during their activities of daily living. Dynamic joint stiffness measurements have taken this limitation into account although they have not estimated the stiffness associated with non-weight bearing motion at the knee (such as the swing phase of gait).

8.7 Clinical relevance

Contrary to the single previous study which has used a control group, this study failed to show evidence of any significant differences in self-reported or performance based measures of function between patients who are 1 year post-TKA and a control group. Whilst it is acknowledged that this small sample may have been skewed towards those with better outcomes, this information could be useful to clinicians involved in preparing patients for surgery and those developing rehabilitation programmes. Pre-operative management of patient expectations of surgery is important, as expectations have been shown to be linked with satisfaction with surgery. Patients expectations were linked to knowledge about the procedure (Hall et al, 2008) and this knowledge came from friends, family and clinicians. Thus up-to-date information on what patients can reasonably expect in the first year post-surgery
will be useful to clinicians in ensuring that patient expectations are reasonable and achievable. This study has shown that although TKA patients continued to demonstrate a reduced range of motion compared to a control group, this did not necessarily impact upon an individuals’ ability to carry out normal daily activities such as walking, stair climbing, and chair transfers at 1 year post-surgery.

One of the most important findings of this study was that there was no evidence of association between patient perceived stiffness and objective measures of stiffness. Forty percent of TKA patients reported some degree of stiffness using the WOMAC scale (question relating to stiffness on waking and after resting) and 85% reported some degree of stiffness using the VAS scale (question relating to stiffness whilst moving around). However of those who reported stiffness, there was no relationship between the severity of the self-reported stiffness and the objective stiffness measures. These results suggested that self-reported stiffness may be influenced by other factors. Furthermore, when participants were asked to select adjectives describe their stiffness, they tended to select words which not only included sensations (such as creaking and grating) but included perceptions of pain (such as hurts, aches and sort) and difficulty with movement (such as limited movements, stiff and restricted). These results indicated that the understanding of stiffness was varied and potentially individual to each participant. This improved understanding of patients experiences of pain and stiffness following surgery will help clinicians to educate patients in what to expect following surgery. Patents appeared to understand ‘stiffness’ to mean a combination of sensations which may have included discomfort and limitations of movement. There is little evidence to show that stiffness was perceived according to the definition of joint stiffness as defined in chapter 4 as the resistance to motion.
Although patients may have had difficulty in distinguishing perceptions of stiffness with perceptions of pain, there was some evidence to suggest that stiffness and function were associated. Patients who perceived they had stiffer knees also demonstrated worse self-reported function and performed worse on the timed tests of function. The exact nature of this relationship is not altogether clear. Studies have shown that self-reported pain and function were closely related (Stratford & Kennedy, 2006) and this study has shown that pain may be a contributor to self-reported stiffness. It could have been concluded from these findings that the relationship between stiffness and function was strongly influenced by pain. However, there appeared to be some association between some of the objective stiffness measures and some of the performance based measures of function. An improved understanding of factors which influence function following TKA is important in helping individuals make the most of the opportunity for an improved quality of life, offered by TKA surgery.

When stiffness threshold angles were normalised there was no difference between groups. All groups showed significant increases in flexion stiffness at around 80% of total passive flexion. This suggested that increasing range of motion would increase the flexion stiffness angle. However, this study found that an increased flexion stiffness angle was associated with worse function. One possible implication for these findings is that clinicians should be cautious about rehabilitation programmes designed to increase knee range of motion without a component to address muscle strength although further work is required to establish a firm link between range of motion, muscle strength and functional ability.
9 Further work

No relationship was seen between self-reported and the objective measures of stiffness, suggesting that patients’ perceptions of stiffness did not arise from bodily structures or physical impairment. Patient perceptions of stiffness were variable and were not limited to sensations of restrictions or slowness in movement (which would have been expected if self-perceived stiffness was associated with the definition of stiffness provided by Physics). Further work should explore further the reasons for the anomaly between self-reported and objective stiffness measures. The approach taken to evaluate self-reported stiffness in this study was quantitative. A qualitative approach however could provide greater evidence into the way that patient interpret stiffness and the impact that it has on their activities of daily living (Ong & Coady, 2006). Britten (1995) noted that interviews are particularly useful to explore behaviour or experience, opinion or belief, feelings and knowledge. Further information on the factors that influence perceived stiffness could help to inform clinicians in planning interventions designed to help patients to maximise their post-operative recovery. Studies have shown self-efficacy to be associated with perceptions of stiffness which further supported the development of the theory that self-perceived stiffness was influenced by psychosocial factors rather than physical impairment. Further work to explore interventions designed to influence self-efficacy and the impact on self-perceived stiffness following TKA could be a useful clinical study.

The potential for objective comparisons in this work was compromised by the high level of variance observed in the objective stiffness measures. Although this may be a reflection of the inter-individual differences previously reported in the literature
(Heerkens, 1985), the work revealed a number of potential sources of error relating to the stiffness rig design that may have contributed to the variance and unless addressed, may threaten the internal validity of future work.

Positioning of the participants – in the current study participants were positioned on the end of a height adjustable plinth. In order to allow sufficient room for full knee flexion to be achieved, the participant did not have the full length of their thigh supported on the plinth. The biomechanical model took into account of the mass of the shank and foot but the positioning of the participant may have meant that the rig also experienced some torque contributed by the mass of the thigh. Therefore further work should be undertaken to consider optimal positioning of the participant. Attachment of the shank and foot to the stiffness rig should also be considered in future work. The lack of support for the thigh mass and the presence of the footplate may have resulted in some additional torque being applied to the rig which was unaccounted for in the biomechanical model. Furthermore there was potential for the footplate to transmit a force to the shank and foot which may have resulted in misalignment of the centre of rotation of the knee and rig. Attachment of the shank and foot along the length of the arm may, in future, help to minimise this problem.

In the current study, only quadriceps muscle activity was monitored in order to assess the passivity of the movement. Knee extension however is limited not by apposition of the soft tissues (as in knee flexion) but by ligaments and the joint capsule (Moore & Agur, 2007). Where the joint is painful (as in OA) or ligamentous restraint is compromised (as in arthroplasty), the hamstrings muscles may be recruited; either voluntarily or involuntarily, in order to provide joint stability. Further work should consider activity in the hamstrings muscles.
Having minimised the contribution of the rig design to the variance, future studies should address other factors that may also have contributed to the variability of the results. The factors may include methods of normalisation of stiffness, the effect of weather, time of day and gender. Stiffness values were normalised to thigh segment mass. It was assumed that the calculation of thigh segment mass based on anthropometric calculations was an appropriate estimation of thigh muscle mass. Anthropometric calculations however were based on participant mass and may have been inaccurate in obese/overweight individuals. Thus future studies may consider the effect of muscle:fat ratios on joint stiffness. Although previous studies have found gender based differences in joint stiffness, this may be associated with muscle mass (Blackburn et al, 2004b). The time of day and weather conditions were also not standardised and future studies may consider the effect of these on the inter-day variability.

It was not the aim of this study to provide an explanation for increased stiffness in TKA patients although some theories have been postulated. Further work could consider exploring these potential reasons in some further depth.

The results of this study also suggested that functional ability may be influenced by stiffness and in particular the stiffness threshold angle. Further work to explore this relationship would provide greater understanding of the factors which influence function following TKA. Function in this study was measured by timed tests of performance. The results of this study indicated that stiffness increases greatly at around 80% of available range of flexion. Other studies have shown that patients only utilised around 80% of their available range of flexion during activities of daily living. A study to explore whether a relationship exists between the stiffness
threshold angle and range of motion utilised during activities of daily living may help to explain why patients fail to utilise available range of motion.

Increased self-reported stiffness was associated with worse functional performance however higher flexion stiffness threshold angles were also associated with worse functional performance. One possible explanation for this has been that sensations of joint laxity and instability result in caution whilst performing sit-stand and stair ascent/descent activities. Participants in this study were not asked to comment on aspects of joint instability and thus further work to explore this hypothesis would be useful.

One of the design features of this study was that the hip was flexed during tests of stiffness and thus inferences of stiffness were limited to activities in which the hip was flexed. Further studies to explore the influence of hip joint position on knee joint stiffness could be useful in establishing the cause of knee joint stiffness and providing further information on how functional activities might be influenced by knee joint stiffness.

Despite the high level of variability in the objective stiffness measures, moderate effect sizes were seen, indicating that with the modifications indicated above, the technique may be useful in identifying inter-group differences. The current study showed a trend towards higher objective measures of stiffness in the TKA group. Sample size analysis showed between groups effect sizes for objective measures of stiffness were medium to large (Cohen, 1992). Based upon these effect sizes, sample size calculations indicated that moderate sample sizes could provide sufficient power to result in statistically significant differences. These results indicated that further work is justified and thus a number of potential hypotheses were proposed:
i. There is a significant difference in knee joint stiffness between participants with end stage OA of the knee, those who have undergone TKA and age matched healthy controls

ii. There is a significant relationship between knee joint stiffness and ability to carry out activities of daily living.
10 Conclusions

This study has been the first to explore stiffness and function following TKA using both self-reported and objective measures. The results supported anecdotal evidence that stiffness is a common complaint both pre and post-TKA. There were however large variations in self reported stiffness, within groups and in particular those awaiting TKA surgery and those who were 1-year post TKA. This may have been related to the fact that in those who reported stiffness, there was little consensus on what participants understood ‘stiffness’ to mean and it is clear from the results that many participants were unable to distinguish pain, difficulty with movement and other sensations. The incidence of true stiffness therefore may be much lower than self-reported measures of stiffness have indicated. In order to get a clear picture of post-operative outcomes, clinicians should take this into account when patients report ‘stiffness’ post-TKA and explore with the patient what ‘stiffness’ means to them.

Large variances were also seen in objective measures of stiffness. Although there were no significant differences in stiffness between groups in this small sample, medium to large effect sizes were seen suggesting that there was a trend to higher stiffness in TKA patients. Furthermore, there were significant differences in the point in range of motion at which flexion stiffness was seen greatly increase. Patients who have undergone TKA surgery can expect to experience greater knee joint stiffness and also stiffness earlier in range of motion. There was no relationship however between objective and self-reported stiffness measures suggesting that any increased stiffness is not necessarily consciously perceived by the patient and further work with larger numbers is required to determine what minimal clinically important differences for objective stiffness. The lack of relationship was however also likely
to have been affected by the participants inability to distinguish stiffness from other
sensations.

In those who reported stiffness, increased self-reported stiffness was associated with
worse self-perceived function and slower timed tests of performance. Functional
ability has been previously shown to be influenced by self-efficacy in OA patients
and further work is required to establish whether increased self-reported stiffness is
similarly associated.
11 References


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Appendix 1 - Torque transducer scaling data

Raw output by angle

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289
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</table>
Bland and Altman Plots of the difference in predicted (applied) torque and actual recorded torque under each weighted condition.

**4.983N**

**10.006N**
Appendix 2 - Reliability of the timed tests of function

Aim

To establish the intra-rater reliability of the researcher with respect to the timed tests of function.

Methods

Twelve healthy volunteers undertook 3 trials of the both the Timed Up and Go and the Time Stair Test. Participants were given the following instructions:

Timed Up and Go – “when I say ‘go’, you should stand up, walk until you reach the marker on the floor, turn around, walk back to the chair and sit down. You should walk at your own speed.”

Stair Ascent – “you should start by standing at the bottom of the stairs with your arms relaxed by your side. When I say ‘go’, go up the stairs and down the other side. You should walk at your own speed using the rails if you feel it necessary.”

A stop watch was used to time the activity. The TUG was timed from the point at which the participants buttocks left the chair until they touched the chair again upon sitting down. The SA was timed from the point at which the first foot left the floor on ascent until the foot first touched the floor on descent.

Intra-class correlation coefficients were used to determine the reliability between the 3 trials. Model (3,1) was used as this is intended for use when the rater is the only rater of interest. In addition, the standard error of measurement was used to determine the amount of the error associated with repeated testing. The ICC was
used and the average standard deviation. The SEM was calculated using the following equation (Stratford, 2004)

$$SEM = 1.96 \times s \sqrt{1-r}$$

**Results**

Table A. Results from all participants for all three trials

<table>
<thead>
<tr>
<th>subject</th>
<th>tug1</th>
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<th>tug3</th>
<th>sa1</th>
<th>sa2</th>
<th>sa3</th>
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<td>4.78</td>
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<td>6.00</td>
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<td>9.24</td>
<td>4.69</td>
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<td>3.22</td>
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<td>6.78</td>
<td>3.94</td>
<td>3.63</td>
<td>4.09</td>
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<td>12</td>
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<td>8.15</td>
<td>4.21</td>
<td>4.34</td>
<td>4.94</td>
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<tr>
<td><strong>Mean</strong></td>
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<td>7.25</td>
<td>7.48</td>
<td>3.95</td>
<td>4.06</td>
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<td><strong>s.d.</strong></td>
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Table B. Inter-trial reliability

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<th>ICC</th>
<th>95% Standard error of measurement (in seconds)</th>
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<td>Timed Up and Go</td>
<td>0.832</td>
<td>0.796</td>
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<tr>
<td>Timed Stair test</td>
<td>0.802</td>
<td>0.464</td>
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Appendix 3 - Visual Analogue Scale for Stiffness

Self-reported Stiffness

Level of Stiffness

Please place a X on the line where you think it best describes your current level of stiffness in the knee that is to be replaced, whilst walking and moving around.

Descriptors of stiffness

From the list of words below, please circle any that you consider to describe your stiffness.

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<th>Limited movement</th>
<th>Hurts</th>
<th>Creaking</th>
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<tr>
<td>Painful</td>
<td>Set</td>
<td>Solid</td>
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<tr>
<td>Stiff</td>
<td>Inflexible</td>
<td>Tense</td>
</tr>
<tr>
<td>Rigid</td>
<td>Fixed</td>
<td>Grinding</td>
</tr>
<tr>
<td>Aches</td>
<td>Locked</td>
<td>Sore</td>
</tr>
<tr>
<td>Stubborn</td>
<td>Immobile</td>
<td>Restricted</td>
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<tr>
<td>Stuck</td>
<td>Tight</td>
<td>Grating</td>
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### Appendix 4 - Tests of normality of distribution

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<td>0.119</td>
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<td>Height (m)</td>
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<td>0.963</td>
<td>0.278</td>
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<td>Mass (kg)</td>
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<td>0.962</td>
<td>0.262</td>
</tr>
<tr>
<td>BMI</td>
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<td>0.944</td>
<td>0.074</td>
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<td>Length of shank and foot (m)</td>
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<td>0.963</td>
<td>0.283</td>
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<tr>
<td>Mass of shank and foot (kg)</td>
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<td>0.962</td>
<td>0.262</td>
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<tr>
<td>Position of centre of mass of shank and foot (distance from proximal joint) (m)</td>
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<td>Radius of gyration (distance from proximal joint) (m)</td>
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<td>0.306</td>
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<td>Thigh circumference (m)</td>
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<td>0.418</td>
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<tr>
<td>Thigh segment mass (kg)</td>
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<td>0.262</td>
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<td>Passive extension (degrees)</td>
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<td>0.864</td>
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<td>Passive flexion (degrees)</td>
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<td>0.012</td>
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<td>Extensor lag (degrees)</td>
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<td>Active flexion (degrees)</td>
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<td>Range of motion (degrees)</td>
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<td>Knee Society Score (o-100)</td>
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<td>WOMAC pain</td>
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<td>&lt;0.001*</td>
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<td>WOMAC function</td>
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<td>WOMAC stiffness</td>
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<td>VAS stiffness(^{25})</td>
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<td>SF-12 PCS</td>
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<td>Timed Up and Go (s)</td>
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<td>0.697</td>
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<td>Walk speed (m/s)</td>
<td>35</td>
<td>0.970</td>
<td>0.454</td>
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\(^{25}\) N > 50, Kolmogorov-Smirnov test used
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<th>N</th>
<th>Mean</th>
<th>SD</th>
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<td>33</td>
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<td>0.476</td>
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<td>Fast flexion stiffness</td>
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<td>0.943</td>
<td>0.119</td>
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<td>Fast extension stiffness</td>
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<tr>
<td>Fast midrange stiffness</td>
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<td>0.977</td>
<td>0.773</td>
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<td>Slow flexion stiffness</td>
<td>30</td>
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<td>0.001*</td>
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<td>Slow extension stiffness</td>
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<td>0.028*</td>
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<td>Slow midrange stiffness</td>
<td>29</td>
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<tr>
<td>Normalised fast flexion stiffness</td>
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<td>0.045*</td>
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<td>Normalised fast extension stiffness</td>
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<td>Normalised slow flexion stiffness</td>
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<td>&lt;0.001*</td>
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<td>0.107</td>
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<td>Fast flexion stiffness angle</td>
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<td>0.636</td>
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<td>0.959</td>
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<td>Slow flexion stiffness angle</td>
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<td>0.957</td>
<td>0.257</td>
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<tr>
<td>Slow extension stiffness angle</td>
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<td>0.067</td>
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<tr>
<td>Normalised fast flexion stiffness angle</td>
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<td>0.096</td>
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<td>0.255</td>
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<td>Normalised slow flexion stiffness angle</td>
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<td>0.946</td>
<td>0.130</td>
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<td>Normalised slow extension stiffness angle</td>
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<td>0.917</td>
<td>0.026*</td>
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<tr>
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<td>0.487</td>
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<td>Fast flexion stiffness torque</td>
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* data not normally distributed
### Appendix 5 - Tests for homogeneity of variance

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<td>Length of shank and foot</td>
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<td>Mass of shank and foot</td>
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Appendix 6 - Tests of gender differences

Results of Mann-Whitney U tests of differences between genders

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<tr>
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<th>Mann-Whitney U statistics</th>
<th>exact p-value</th>
<th>Cliff’s δ</th>
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<tr>
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* = significant (p < 0.05) gender differences
Results of independent t-tests of differences between genders

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<td>1.356</td>
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<td>Fast flexion stiffness</td>
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<td>-0.637</td>
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<td>Fast midrange stiffness</td>
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<td>1.000</td>
<td>0.00</td>
</tr>
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<td>Normalised stiffness slow extension</td>
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<td>Fast extension stiffness angle</td>
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<td>0.729</td>
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<td>Fast flexion stiffness torque</td>
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<td>0.779</td>
<td>0.111</td>
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</table>

† = significant (p < 0.05) gender differences
Appendix 7 - WOMAC scores

WOMAC

All participants (n = 35) completed the WOMAC questionnaires which were reported here according to the original scoring system (Bellamy, 2000) as well as normalised to a 0-100 scale. The scales of the individual WOMAC domains are 0-20 (pain), 0-8 (stiffness) and 0-68 (function) where higher scores represent greater pain, stiffness and functional limitations.

WOMAC scores were not normally distributed and were therefore presented as median and IQR (Table C).

Table C. WOMAC scores by group

<table>
<thead>
<tr>
<th></th>
<th>WOMAC_{pain}</th>
<th>WOMAC_{stiffness}</th>
<th>WOMAC_{function}</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>0.00 (1.00)</td>
<td>0.00 (1.00)</td>
<td>0.00 (8.75)</td>
</tr>
<tr>
<td>OA</td>
<td>9.5 (7.75)</td>
<td>3.50 (5.50)</td>
<td>35.00 (18.00)</td>
</tr>
<tr>
<td>TKA</td>
<td>1.00 (3.00)</td>
<td>0.00 (2.00)</td>
<td>10.00 (8.00)</td>
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</table>

A WOMAC pain score of 0 indicated no pain. Fifty-eight percent (n = 7) of participants in the control group and 48% (n = 7) of participants in the TKA reported no pain compared to 0% in the OA group. The Kruskall-Wallis test showed significant differences in WOMAC pain between the groups ($\chi^2 = 17.898$, df = 2, $p < 0.001$). Post-hoc analyses indicated that the OA group had significantly greater pain ($p < 0.001$) than either the TKA or control. There were no significant differences between the TKA and control groups ($p = 0.028$) once a Bonferroni correction had been applied.
A WOMAC function score of 0 indicated no functional limitations. Forty-two percent of the control group reported some functional limitations (WOMAC score > 0) compared to 100% of the OA group and 87% of the TKA group. These differences were statistically significant (Fishers Exact test = 9.406, p = 0.008).

The Kruskall-Wallis test showed significant differences in WOMAC function between groups ($\chi^2 = 15.842$, df = 2, $p < 0.001$). Post-hoc analyses showed that the OA group reported significantly greater ($p < 0.001$) functional limitations than either the TKA or control group. No significant differences were found in WOMAC function between the TKA and control group ($p = 0.548$).

The WOMAC stiffness score indicated that, sixty-seven percent of the control group (n = 8) and 60% of the TKA group (n = 9) reported no stiffness compared to only 25% of the OA group (n = 2). There was no significant difference in the proportion of participants reporting any stiffness using the WOMAC scale (Fishers Exact test = 3.533, $p = 0.196$).

The Kruskall-Wallis test showed no significant differences between groups in WOMAC stiffness ($\chi^2 = 5.905$, df = 2, $p = 0.052$). There was one significant outlier in the control group. As the Kruskall-Wallis test had shown a p-value which lay just outside the level set for significance, the data was reanalysed with this outlier removed to determine the effect of this outlier on the overall significance of the differences. With the outlier removed, the Kruskall-Wallis test showed significant differences between the groups in WOMAC stiffness ($\chi^2 = 7.780$, df = 2, $p = 0.020$). Post-hoc analysis indicated that that control group had significantly lower stiffness than the OA group but no other significant between group differences were observed.
Normalised WOMAC scores were not normally distributed and therefore data were presented as median and interquartile range. All scores are on a scale of 0 – 100 where 0 represented no pain, no stiffness and no functional limitations, 100 represented maximum pain, maximum stiffness and maximum functional limitations.

Table D. Normalised WOMAC scores by group

<table>
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<tr>
<th></th>
<th>nWOMAC&lt;sub&gt;pain&lt;/sub&gt;</th>
<th>nWOMAC&lt;sub&gt;stiffness&lt;/sub&gt;</th>
<th>nWOMAC&lt;sub&gt;function&lt;/sub&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>0.00 (5.00)</td>
<td>0.00 (12.50)</td>
<td>0.00 (12.87)</td>
</tr>
<tr>
<td>OA</td>
<td>47.50 (38.75)</td>
<td>43.75 (68.75)</td>
<td>51.47 (26.47)</td>
</tr>
<tr>
<td>TKA</td>
<td>5.00 (15.00)</td>
<td>0.00 (25.00)</td>
<td>14.71 (11.76)</td>
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</table>
Appendix 8 - SF-12 scores

The SF-12 questionnaire was scored to produce two domains – the physical component summary (PCS) and the mental component summary (MCS). Data was normally distributed and is therefore presented as mean (sd). One participant in the OA group chose not to complete the questionnaire (n = 7). All other group participants completed the SF-12 (control, n = 12; TKA, n = 15). Bar charts (Figures A & B) show the mean PCS and MCS scores. Error bars indicate ± 1 sd. The heavy black line bisecting the y-axis indicates the population norm and the two dashed lines indicate the population 95% confidence intervals.

Figure A. Mean PCS scores by group
One participant from the control group, 2 from the OA group and 1 from the TKA group had a PCS score which lay below the lower bound of the 95% CI. All other participants lay within the lower and upper bounds. A one-way ANOVA (assumption of homogeneity of variance met – Appendix 5) showed significant differences between the groups in the PCS ($F(2,31) = 3.545, p = 0.041$, $\omega^2 = 0.130$). Post-hoc Tukey’s tests showed that significant differences lay between the control and OA groups ($p = 0.017$) and TKA and OA groups ($p = 0.028$). There were no significant differences between control and TKA ($p = 0.726$).

The OA and TKA groups reported mental health scores which were above the population norm i.e. better mental health than the average. All three groups however reported mean scores which were inside the population 95% confidence intervals (Figure B). One-way ANOVA (assumption of homogeneity met – Appendix 5) showed that there were no significant differences in the MCS between groups ($F(2,31) = 2.376, p = 0.110$).
Figure B. Mean MCS scores by group

As MCS showed no significant difference between groups and was normally distributed, confidence intervals of the differences between pairs of groups were constructed. The 95% CI of the differences show that 0 lay within the upper and lower bound in all cases confirming that there were no significant differences between groups.

Table D. 95% confidence intervals of the difference in MCS between groups

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<th>95% CI of the difference</th>
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<td>-15.605, 1.572</td>
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<tr>
<td>Control – TKA</td>
<td>-10.414, 0.089</td>
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<tr>
<td>OA - TKA</td>
<td>-8.724, 11.982</td>
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</table>
Appendix 9 - Scatterplots of stiffness by function