Graft tensioning in anterior cruciate ligament reconstruction

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Master of Physiotherapy; Bachelor of Exercise Science

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The University of Queensland in 2015

School of Health and Rehabilitation Science
Abstract

Background
Anterior cruciate ligament reconstruction (ACLR) is an effective procedure for restoring stability and function. Being a technically demanding procedure, patient outcomes are highly dependent on numerous surgical factors, which are critical for success. The application of tension to the graft prior to tibial fixation is one such factor and is considered essential for the restoration of joint stability, normal knee biomechanics, graft revascularisation and patient function. In applying tension, a key factor is the amount of force applied to the graft. However, the method of applying the tension, position of the knee during tensioning, properties of the graft material, tunnel placement and graft fixation device can all influence the effect that graft tension has on outcomes. Despite the reported importance of graft tension there has been limited empirical evidence defining the best tensioning practice for restoring patient outcome post ACLR.

Aims
The goal of this program of research was to explore the effect that different aspects of graft tensioning has on patient function post ACLR. To address the aims of the thesis, three studies were conducted. The first study was a systematic review aimed at examining if a particular amount of tension results in better functional outcomes post ACLR. The second study aimed to compare the effect of two methods of applying graft tension on patient function post ACLR. The study used a prospective randomised controlled trial to compare manual tensioning with the use of a tensioning device. The third study aimed to define current graft tensioning practices and explore the factors that influence surgical decision making. A national survey of Australian orthopaedic surgeons was conducted to achieve the aims of the study.

Results
The systematic review (study one) revealed that a medium graft tension of 79N to 90N produced the least side-to-side difference (STSD) in anterior posterior (AP) tibial translation as measured by a KT-1000 when compared to tensions <79 or >90N. However, the heterogeneous use of functional outcomes inhibited the ability to draw conclusions on other patient specific functional outcomes. Furthermore, the review highlighted the lack of high quality studies, which also failed to discuss other aspects of graft tension such as the method of applying tension.
Building on the findings of study one, the second study undertook a RCT to compare the functional outcomes of applying 80N of force with a tensioning device (TD) \((n=10)\) to a manual tensioning method (MT) \((n=13)\) using an estimated force described as a sustained maximum one handed pull. Patients were assessed at pre-surgery and two weeks, three months, six months and 12 months post surgery. The International Knee Documentation Committee Score (IKDC) was selected as the primary outcome measure. Secondary outcomes were the Lysholm score, Tegner score, single leg hop test for distance (SLHD) and STSD in AP tibial translation as measured by a KT-1000. Linear mixed model statistics on continuous variables demonstrated no significant difference between groups for the IKDC, Tegner, SLHD or STSD in AP tibial translation.

Based on the findings of study one, tensioning between 79N and 90N appeared to improve the restoration of joint stability, when compared to higher and lower tensions. However, no effect on patient function within 24 months post surgery was apparent. Furthermore, study two observed that tension did not appear to have an effect on patient function at 12 months post surgery. With no clear difference in functional outcomes, a national survey of experienced orthopaedic surgeons was conducted to understand the factors that impacted on the amount and type of tension used during surgery. The results of the survey demonstrated that MT, using a maximum one handed pull, near full knee extension with a semitendinosus gracilis (STG) autograft was the most common method of tensioning. However, the estimated force applied to the graft varied from <20N to >133N among surgeons using a MT method and an estimated force between 41N and 60N was most commonly reported. In the TD group, a measured mean (SD) tension of 81.9(29.56)N was reported. Surgeons perceived that their tensioning practice was influenced mostly by experience with previous patient outcomes and available evidence. In addition, the MT group reported surgical training as an influencing factor compared to the TD group who reported accuracy as an important influence on method.

**Conclusions**

This program of research suggests that a graft tension between 79N and 90N results in reduced STSD in AP tibial translation when compared to tensions <79N or >90N. The use of a tensioning device may assist in achieving a consistent tension and thus reduce post surgical laxity. However, there was no evidence to support the selection of one approach over another post ACLR. Current clinical practice appears to be influenced predominantly by perceived patient outcomes rather than definitive evidence, indicating a need for further research. Studies that include longitudinal methodologies and functional measures sensitive to the effect of tensioning would assist in determining an optimal tensioning protocol.
Declaration by author

This thesis is composed of my original work, and contains no material previously published or written by another person except where due reference has been made in the text. I have clearly stated the contribution by others to jointly-authored works that I have included in my thesis.

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Peer-reviewed papers


Conference Presentations


Poster Presentations


Publications included in this thesis


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Contributions by others to the thesis

In their role as principal supervisors, Associate Professor Trevor Russell and Professor Lucy Chipchase contributed to the overall concept of the thesis, assisted in the interpretation and analysis of data, developed academic writing skills and provided valuable mentorship to the candidate on the skills and attributes necessary for the awarding of a PhD.

As co-supervisor Dr Michael Bourke assisted in delivering the above roles under the guidance of the principal supervisors as well as playing a key role in the initial development and implementation of this body of work.

Dr Philip Dalton played an integral role as the primary orthopaedic surgeon providing expert opinion on matters relating to surgical procedure throughout the thesis, conducting the surgical procedures for the randomised clinical trial, assisting with accessing professional networks to conduct the survey and providing support and mentorship in the field of Orthopaedic research. Dr Mark Dekkers also contributed to the conducting of surgical procedures as part of the randomised controlled trial.

Statement of parts of the thesis submitted to qualify for the award of another degree

No part of the thesis was submitted to qualify for the award of another degree.
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My PhD journey has been a long and winding road; however, now that I have reached my destination I can appreciate the many skills and experiences I have learnt along the way. The achievement of such a body of work has been attributable to the significant contribution of my three supervisors, professional colleagues and my family and friends who have provided unwavering support throughout the process.

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My final and most important acknowledgements are reserved for that of my family. To my parents Cathy and Charlie, you have given me every opportunity in life and I wouldn’t be the person I am today without your influence. To my wonderful wife Liz, who patiently put up with the long days and supported my goal unquestionably with nothing but love and support. Finally, Tyler, Isabel and Olivia, your smiling faces made every day brighter and I ultimately dedicate this to you!
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<tr>
<td>ACL</td>
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<td>ACLR</td>
<td>Anterior cruciate ligament reconstruction</td>
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<td>AHPRA</td>
<td>Australian Health Practitioner Regulation Authority</td>
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<td>AKS</td>
<td>Australian Knee Society</td>
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<td>ANOVA</td>
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<td>AOA</td>
<td>Australian Orthopaedic Association</td>
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<tr>
<td>AP</td>
<td>Anterior-posterior</td>
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<td>AM</td>
<td>Anteromedial</td>
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<tr>
<td>BMI</td>
<td>Body Mass Index</td>
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<tr>
<td>BPTB</td>
<td>Bone patella tendon bone</td>
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<tr>
<td>CI</td>
<td>Confidence interval</td>
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<td>CINAHL</td>
<td>Cumulative Index to Nursing and Allied Health Literature</td>
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<td>CSA</td>
<td>Cross sectional area</td>
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<td>DoF</td>
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<td>ESSKA</td>
<td>European Society of Sports Traumatology, Knee Surgery and Arthroscopy</td>
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<td>Gr</td>
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<tr>
<td>ICC</td>
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<td>ICF</td>
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<td>International Knee Documentation Committee</td>
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<td>Knee Osteoarthritis Outcome Score</td>
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<td>MCID</td>
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<tr>
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<td>QoL</td>
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PCL  Posterior cruciate ligament
PeDro  Physiotherapy evidence database
PL  Posterolateral
PRISMA  Preferred Reporting Items for Systematic Reviews and Meta-Analysis
ROM  Range of movement
SD  Standard deviation
SEM  Standard error of measure
SLHD  Single leg hop test for distance
SMD  Standardised mean difference
STG  Semitendinosus Gracilis
STSD  Side-to-side difference
TD  Tensioning device
TF  Tibio-femoral
WHO  World Health Organisation
WOMAC  Western Ontario and McMaster Universities Osteoarthritis Index
1 Introduction

Anterior cruciate ligament reconstruction (ACLR) is widely accepted in the treatment of ACL rupture, with more than 10,000 procedures performed annually in Australia (Janssen, Orchard, Driscoll, & van Mechelen, 2012). Surgical reconstruction aims to restore stability, limit further injury, improve function and reduce the risk of degenerative joint disease (Janssen et al., 2012; Lewis, Parameswaran, Rue, & Bach, 2008; Sajovic, Strahovnik, Dernovsek, & Skaza, 2011). In order to achieve such outcomes, current surgical practice aims to replicate the native ACL to restore stability and normal biomechanics. However, current research reports that up to 40% of patients do not reach their previous level of function and up to 50% are at risk of osteoarthritis (OA) despite surgical intervention (Biau, Tournoux, Katsahian, Schranz, & Nizard, 2007; Meunier, Odensten, & Good, 2007).

Surgical reconstruction of the ACL is a technically difficult procedure with success dependent upon multiple factors. Graft choice, tunnel placement, graft tension and graft fixation are all considered important for achieving an optimal outcome (Woo, Wu, Dede, Vercillo, & Noorani, 2006). Considered a critical step, the process of graft tensioning is primarily dependent on the force applied to the graft prior to tibial fixation; however, the method in which the force is applied and the angle at which the knee is positioned during tensioning are also important considerations. It has been hypothesised that insufficient tension results in an under-constrained knee, leading to instability, poor graft healing and, ultimately, a poorer outcome (Boylan, Greis, West, Bachus, & Burks, 2003; Kim, Kurosawa, Sakuraba, Ikeda, & Takazawa, 2006). Excessive tension on the other hand is thought to over-constrain the knee, resulting in impaired range of motion (ROM), increased joint compression and a greater risk of graft failure (Boylan et al., 2003; Kim et al., 2006). Thus, optimal graft tension is an important factor in the restoration of stability, biomechanics and function; and a critical factor for superior outcomes (Thompson, Hull, & Howell, 2006).

Despite its recognised importance, there is a paucity of empirical evidence defining the amount of tension, the best method to apply the tension or the ideal angle of knee flexion to produce an optimal outcome. van Kampen, Wymenga, van der Heide, and Bakens (1998) concluded that 20N of tension, applied at 20 degrees flexion, using a bone-patella tendon-bone (BPTB) autograft was
sufficient to achieve a successful outcome. In contrast, Nicholas et al. (2004) reported 45N was insufficient and 90N applied at full extension was better able to restore stability when using the same graft. In studies investigating the semitendinosus gracilis (STG) autograft a similar disparity can be observed. Yasuda, Tsujino, Tanabe, and Kaneda (1997) concluded that 80N was superior at restoring laxity compared to 20N. Whereas Kim et al. (2006) reported no difference between 78.5N and 147.1N both applied at 30 degrees of knee flexion. With conflicting evidence and a lack of clarity on best practice, many surgical decisions regarding graft tensioning are based on tacit knowledge and clinical experience.

1.1 Thesis aims and hypotheses

The aims of the thesis were to investigate how various aspects of graft tensioning effect patient outcomes post ACLR. Three primary studies were completed to address the following aims and hypotheses.

**Aim 1:** Investigate the current evidence to determine the influence of graft tension on patient outcomes post ACLR, using a systematic literature review.

**Hypothesis 1:** A medium tension range will result in a better functional outcome when compared to low and high tension.

This aim and hypothesis is addressed in Chapter 3 of the thesis.

**Aim 2:** To compare the functional outcomes between grafts manually tensioned using a maximum one-handed pull with those tensioned at 80N using a tensioning device, 12 months post ACLR.

**Hypothesis 2:** Those tensioned with a device will have better functional outcomes than those manually tensioned post ACLR.

This aim and hypothesis is addressed in Chapter 4 of the thesis.

**Aim 3:** Define current clinical practice among Australian orthopaedic surgeons with respect to graft tensioning and investigate factors that influence practice.
Hypothesis 3: A manual method of tensioning, applied at near full extension will be most prevalent among Australian orthopaedic surgeons, however, clinical practice will vary within the population.

This aim and hypothesis is addressed in Chapter 5 and Chapter 6 of the thesis.

1.2 Thesis outline

Chapter 2 presents the reader with a relevant background to the thesis and provides a critical review of the available literature relating to ACL injury and management. A brief introduction to the biomechanics of the ACL and related mechanisms of injury are provided, followed by an in-depth overview of assessment and management of ACL rupture. Chapter 3 reports the findings of a systematic review investigating the effect of graft tension amount on functional outcomes post ACLR. Chapter 4 outlines the intentions for conducting a RCT and reports the study complications to accurately interpret the study findings. Chapter 5 reports the findings of a randomised controlled trial comparing methods of tensioning and their effect on functional outcome post ACLR. Chapter 6 outlines the methodology for the development and validation of a national survey on graft tension and functional outcomes post ACLR. Results from the study demonstrating validity and reliability are presented and evidence based recommendations provided for conducting a national survey. Chapter 7 details the findings of a national survey on orthopaedic surgical practice and perceptions on graft tension and functional outcome. As each study stands alone, the findings of each study are presented and discussed separately first. Then, the final chapter (Chapter 8) addresses the implications, limitations and clinical relevance of the thesis to provide recommendations for future directions in this field.

References cited in this thesis are presented as a continuous list at the conclusion of the thesis to avoid repetition and improve readability.
2 Anterior cruciate ligament Injury

The aim of the chapter is to present the reader with the necessary background on anterior cruciate ligament (ACL) injury and intervention with specific reference to the surgical procedure. The opening section provides an introduction to the anatomy and biomechanics of the ACL with a focus on topics important to the surgical reconstruction. Mechanisms of injury and the functional implications of ACL rupture are then presented, with the relevant outcome measures that evaluate the effectiveness of intervention discussed. Interventions are introduced broadly in terms of conservative and surgical methods; however, surgical methods form the primary focus of intervention in line with the aims and objectives of the thesis.

2.1 Anatomy, biomechanics and mechanism of injury

2.1.1 Anatomy

The ACL originates within the inter-condylar notch of the postero-medial aspect of the lateral femoral condyle and inserts at the antero-lateral aspect of the inter-condylar area on the tibia [Figure 2-1] (Dargel et al., 2007; Markatos, Kaseta, Lallos, Korres, & Efstathopoulos, 2013; Woo et al., 2006). Enveloped by the synovium of the knee and classified as an intra-articular but extra-synovial structure (Zantop, Petersen, Sekiya, Musahl, & Fu, 2006), the ACL is vascularised via the middle genicular artery and innervated by the posterior branches of the tibial nerve (Duthon et al., 2006). The native ACL ranges from 32 – 41 mm in length (Bicer, Lustig, Servien, Selmi, & Neyret, 2010). In cross-section, the smallest part of the ligament is at the mid-substance, measuring between 36 and 48.9 mm² (Bicer et al., 2010), and the insertion sites are approximately 3.5 times greater in area (Harner et al., 1999). Structurally, the ligament is obliquely orientated within the knee and divided into collections of fascicles termed bundles (Arnoczky, 1983). Two functional bundles, named in relation to their tibial insertion, are referred to as the anteromedial (AM) and posterolateral (PL) bundles (Arnoczky, 1983; Duthon et al., 2006; Girgis, Marshall, & Monajem, 1975). A third intermediate bundle has been discussed in cadaver-based studies (Kato et al., 2012; Norwood & Cross, 1979). However, conflicting results in recent studies have questioned the functional
relevance and, hence, it is rarely referred to within ACL literature (Mackay, Whitehead, & Toms, 2014).

**Figure 2-1: Placement and orientation of the ACL**

The tibial insertion of the ACL is considered the broadest part of the ligament and is described as either oval or triangular in shape (Bicer et al., 2010; Harner et al., 1999). Located in the anterior intercondylar fossa of the tibia and antero-lateral to the medial tibial spine, the area covered by the ACL is 7 – 16 mm medial to lateral and 9 – 19.5 mm anterior to posterior (Hwang, Piefer, & Lubowitz, 2012). The AM and PL bundles are positioned accordingly within the tibial footprint with the AM bundle typically larger [Figure 2-2] (Hwang et al., 2012; Kopf, Pombo, Szczodry, Irrgang, & Fu, 2011).
Figure 2-2: Tibial insertion of the ACL

Femoral insertion of the ACL is located on the posterior aspect of the inner lateral femoral condyle (Dienst, Burks, & Greis, 2002; Duthon et al., 2006; Zantop et al., 2006) and bordered by the lateral inter-condylar ridge and lateral bifurcate ridge (Kopf et al., 2011). Described as a circle segment or oval shape, the size of the ACL at insertion ranges between 12.9 – 17.2 mm proximal to distal and 6.8 – 9.9 mm anterior to posterior (Piefer, Pflugner, Hwang, & Lubowitz, 2012), accounting for 45 – 75 % of the lateral femoral notch (Dienst et al., 2002). Within the femoral footprint, the AM bundle is positioned proximal and anterior relative to the PL bundle, which is posterior and inferior [Figure 2-3] (Bicer et al., 2010).
2.1.2 Biomechanics of the ACL

The tibio-femoral (TF) joint exhibits three degrees of translation (anterior-posterior, medial-lateral, proximal-distal) and three degrees of rotation (flexion-extension, external-internal, abduction-adduction), allowing 12 possible movements (Dienst et al., 2002). Collectively, all ligamentous structures of the knee provide stability for each motion (Fu, Harner, Johnson, Miller, & Woo, 1993). Specifically, the ACL provides primary stability for anterior tibial translation and secondary stability for internal tibial rotation and medial tibial translation (Dienst et al., 2002; Quatman, Quatman-Yates, & Hewett, 2010).

The anatomical position and fascicle orientation of the AM and PL bundles lengthen and tension at different ranges of knee motion (Gabriel, Wong, Woo, Yagi, & Debski, 2004). As illustrated in Figure 2-4, under 134N of anterior load the in-situ force within the ligament shifts from the PL bundle in extension to the AM bundle in flexion, with minimal tension experienced at approximately 15 degrees as the load is transferred from the PL to AM bundle (Gabriel et al., 2004). This biomechanical pattern allows the ACL to provide stability throughout range to allow dynamic functional movements.
2.1.3 Mechanism of injury

Injury to the ACL occurs as a result of excessive force in anterior tibial translation, internal tibial rotation and/or valgus angulation (Jones & Rocha, 2012; Yu, 2007). The force required to rupture the native ACL appears to be dependent on age (Duthon et al., 2006). The average anterior failure load in a person aged between 22 and 35 years old is 2160N compared to 658N for 60 to 97 year old person. Similarly, an average rotational force of 242N/m and 180N/m is required for rupture in 22 to 35 and 60 to 97 year old person respectively (Woo, Hollis, Adams, Lyon, & Takai, 1991). A force resulting in rupture can either be contact (e.g. secondary to a collision) or non-contact (e.g. pivoting motion) (Jones & Rocha, 2012; Yu, 2007), with non-contact mechanisms generally considered most common, depending on the activity (Gianotti, Marshall, Hume, & Bunt, 2009; Granan, Inacio, Maletis, Funahashi, & Engebretsen, 2013; Kobayashi et al., 2010).

The classic description given by patients of their ACL injury includes a pivoting or cutting manoeuvre associated with a rapid change in direction or landing, where the weight-bearing limb is described as ‘giving way’ (Kobayashi et al., 2010). A recent review by Quatman et al. (2010) evaluated the evidence on injury patterns in ACL to describe the most likely mechanisms resulting in ACL rupture. Summarised in Table 2-1, the review detailed how each of the 12 knee motions affected the ACL and highlighted the secondary factors associated with increased load (Quatman et al., 2010). The primary biomechanical sequence found most likely to result in ACL rupture was (1) anterior tibial translation with the knee flexed between $10^\circ$ and $30^\circ$ in the sagittal plane; (2) internal
rotation of the tibia with TF compression in the transverse plane; (3) abduction and medial tibial translation in the frontal plane; and (4) a forcefully contracting quadriceps muscle (Granan et al., 2013; Kobayashi et al., 2010; Quatman et al., 2010; Yu, 2007).
<table>
<thead>
<tr>
<th>Plane</th>
<th>Rotation</th>
<th>Translation</th>
</tr>
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<tbody>
<tr>
<td>Sagittal</td>
<td><strong>Flexion</strong></td>
<td><strong>Secondary factors</strong></td>
</tr>
<tr>
<td></td>
<td>Strain increases into end of range flexion primarily on AM bundle</td>
<td>Anterior</td>
</tr>
<tr>
<td></td>
<td><strong>Extension</strong></td>
<td>Quadriceps contraction</td>
</tr>
<tr>
<td></td>
<td>Strain increases into hyperextension primarily PL bundle</td>
<td>Internal rotation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Posterior</td>
</tr>
<tr>
<td>Frontal</td>
<td><strong>Abduction</strong></td>
<td>Simultaneous Quads contraction</td>
</tr>
<tr>
<td></td>
<td>Greatest strain near full extension</td>
<td>Increases strain 100%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Medial</td>
</tr>
<tr>
<td></td>
<td><strong>Adduction</strong></td>
<td>Minimal effect</td>
</tr>
<tr>
<td></td>
<td>Minimal effect</td>
<td>Lateral</td>
</tr>
<tr>
<td>Transverse</td>
<td><strong>Internal</strong></td>
<td>Strain greater at lower angles of flexion</td>
</tr>
<tr>
<td></td>
<td>Strain increases into end of passive range</td>
<td>Compression</td>
</tr>
<tr>
<td></td>
<td><strong>External</strong></td>
<td>Distraction</td>
</tr>
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<td></td>
<td>Minimal effect</td>
<td></td>
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</tbody>
</table>

**Abbreviations:** AM – anteromedial, PL – posterolateral, ACL – anterior cruciate ligament

*Table adapted from Quatman et al. (2010)*
2.2 Disability associated with anterior cruciate ligament rupture

Evaluating the broad impact that ACL deficiency has on a person both functionally and socially is imperative for successful management. Furthermore, an understanding of disability provides a basis for determining intervention and the methods upon which to evaluate effectiveness (Ardern, Webster, Taylor, & Feller, 2011; Irrgang, 2008; Pantano et al., 2001). In order to define disability, the World Health Organisation (WHO) introduced the International Classification of Functioning (ICF) (2001), which provides a universally recognised framework that can be applied to the ACL deficient knee (Ardern et al., 2011; Pantano et al., 2001). In applying an ICF model to categorise disability, in conjunction with valid and reliable outcome measures, the clinician can implement a patient focused intervention with an accurate method to evaluate the efficacy.

2.2.1 The WHO ICF as a model for disability in ACL rupture

The WHO ICF (2001) provides a biopsychosocial framework to classify function and disability as a consequence of pathology or impairment (Ardern et al., 2011; Pantano et al., 2001). Figure 2-5 demonstrates how ACL rupture results in a range of physical impairments, which affect the functional capacity of the person and result in a restriction to participation (Ardern et al., 2011; Irrgang, 2008; Pantano et al., 2001). Significant physical, social and economic implications result from ACL rupture. In fact, a recent study estimated the total cost of ACL injury in Australia at greater than $100 million per annum (Janssen et al., 2012; Mather et al., 2013). Therefore, accurate and quantifiable measures for the assessment of disability and the evaluation of intervention are paramount in minimising the impact associated with ACL rupture (Ardern et al., 2011; Irrgang, 2008; Pantano et al., 2001).
2.2.2 Assessing impairment

Impairment is defined by the ICF as a problem in body function and structure such as significant deviation or loss (Woo et al., 2006; World Health Organisation, 2013). In the case of ACL rupture, knee function is limited due to structural interruption of the ligament, resulting in significant anterior and rotational instability as well as valgus instability. Although rotational and anterior instability are both critical to evaluating function, quantifying rotational instability is challenging in comparison to anterior instability. Therefore, the primary clinical measure for evaluating the ACL deficient knee has predominantly focused on anterior instability (Duthon et al., 2006; Hanten & Pace, 1987; Torg, Conrad, & Kalen, 1976). The anterior drawer, Lachman’s test and the pivot shift test are the three most commonly reported and widely accepted clinical tests for assessing anterior stability (Peeler, Leiter, & MacDonald, 2010).

**Anterior drawer**

The anterior drawer test is the earliest reported clinical measure for the diagnosis of ACL instability (Hanten & Pace, 1987; Torg et al., 1976). The test is performed with the person in supine and the hip and knee flexed to 45 and 90 degrees, respectively. The clinician applies an anterior force to the tibia while stabilising the foot [Figure 2-6]. A positive sign is characterised by excessive anterior
translation of the tibia on the femur when compared to the unaffected side (Benjammse, Gokeler, & van der Schans, 2006; Torg et al., 1976).

**Figure 2-6: Anterior Drawer Test**

![Diagram of Anterior Drawer Test](image)

**Lachman’s test**

An evolution of the anterior drawer test, as described by Torg et al. (1976), the Lachman’s test assesses the person in supine with the leg flexed to between 20 and 30 degrees. One hand stabilises the femur while the other hand is placed posterior to the proximal tibia and a firm anterior force is applied [Figure 2-7]. A ‘soft’ end feel, that is in contrast to the ‘hard’ end feel in the normal knee, plus an observed anterior laxity, indicate a positive test (Benjammse et al., 2006; Torg et al., 1976).
**Pivot shift test**

Galway and Macintosh (1980) first described the pivot shift test to assess anteromedial and rotational instability of the knee. To elicit the pivot shift, the person is placed supine and the clinician lifts the leg by the ankle with the knee extended. Internal or external rotation of the tibia applied to bias posteromedial or posterolateral structures, respectively. The other hand is placed behind the proximal fibula, applying a valgus strain while the knee is moved from extension into flexion [Figure 2-8]. A positive pivot shift is defined as sudden reduction of the anteriorly subluxed tibial plateau and can be graded as I, II or III as described in Table 2-2 (Benjamms et al., 2006; Galway & Macintosh, 1980).
Table 2-2: Grading of the pivot shift test

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
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<tbody>
<tr>
<td>Grade I</td>
<td>Reduction of the tibia is gentle and barely palpable and only present with maximum internal rotation</td>
</tr>
<tr>
<td>Grade II</td>
<td>Reduction of the tibia occurs in neutral and moderate internal rotation with a definite clunk apparent with internal rotation</td>
</tr>
<tr>
<td>Grade III</td>
<td>Reduction of the tibia occurs with neutral, moderate internal and external rotation with the presence of a pronounced clunk</td>
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</tbody>
</table>

Validity and reliability of impairment testing

All three tests have been widely reported and studied in the literature since their inception (Benjammse et al., 2006). Based on the findings of Benjammse et al. (2006), the anterior drawer test is considered the least accurate of the three clinical tests. Meta-analysis reported a pooled sensitivity of 55% (95% CI 52 – 58) and specificity of 92% (95% CI 90 – 94), indicating a poor ability to detect an ACL rupture. Similarly, the Pivot shift test exhibited low sensitivity (25%; 95% CI, 21-27); however, demonstrated high specificity (98%; 95% CI, 96-99), indicating a strong ability to rule out an ACL rupture. The Lachman’s test demonstrated both a high sensitivity (85%,
95% CI 83 – 87) and specificity (94%, 95% CI 92 – 95) (Benjammse et al., 2006; Scholten et al., 2003). The fact that maximal tension in the majority of the ligament is achieved during the Lachman’s test, a sudden qualitative end point is consistently observed in an intact ACL resulting in high specificity (Rosenberg & Rasmussen, 1984). In addition, as flexion range increases the tension on the ACL during anterior load reduces, resulting in a greater risk of a false negative due to the effect of secondary constraints such as the medial meniscus, capsular ligaments and condylar geometry (Rosenberg & Rasmussen, 1984). For these reasons, the Lachman’s test has been recognised as the preferred test in assessing the integrity of the ACL (Benjammse et al., 2006; Rosenberg & Rasmussen, 1984; Scholten et al., 2003).

While the Lachman’s test shows good sensitivity and specificity for the assessment of impairment associated with ACL rupture, it does not provide an objective and quantifiable measurement of anterior-posterior (AP) laxity. In response, Daniel, Stone, Sachs, and Malcom (1985) proposed the use of instrumented laxity devices to measure anterior laxity of the knee. The MEDmetric Corporation, San Diego, California produced the KT-1000 instrumented knee laxity device, which measures the amount of anterior tibial translation at the knee. Although other instrumented devices are available, over the past 29 years, the KT-1000 has been the most widely researched outcome measure for AP laxity in ACL rupture (van Eck, Loopik, van den Bekerom, Fu, & Kerkhoffs, 2013).

**KT-1000 knee arthrometer**

The KT-1000 is attached to the tibia with the person in supine and the knee flexed between 20 and 30 degrees. The clinician aligns the device accordingly and two feelers are placed at the proximal tibia and patella. A stabilising force is applied to the feeler located over the patella while the clinician applies an anterior force. A load of 15 pounds, 20 pounds or 30 pounds can be applied as indicated by a beep emitted from the device. In addition, by placing the hand on the posterior aspect of the proximal tibia and forcing the tibia anteriorly, a maximum manual force can be applied. The amount of anterior tibial displacement can be measured in millimetres at each force applied [Figure 2-9]. Appendix A describes the full process for standardised application and use of the KT-1000. A positive result is defined as greater than 3mm side-to-side difference (STSD) in anterior tibial translation between the affected and non-affected limb and is indicative of an ACL deficient knee (Arneja & Leith, 2009; Daniel et al., 1985; Irrgang, 2008).
As a diagnostic tool, the KT-1000 at maximum manual force has a very high sensitivity (93%) and specificity (93%) (van Eck et al., 2013). When conducted by an experienced tester, the KT-1000 also has a high degree of intratester reliability (ICC 0.90 – 0.99; SEM 0.3 – 0.6 mm) (Berry et al., 1999). The ability to deliver a quantifiable and accurate measure of laxity has seen use of the KT-1000 proliferate as an outcome measure in the literature for ACL injuries (Benjammse et al., 2006; Scholten et al., 2003). With AP instability being one of the primary impairments of an ACL deficient knee, the ability to quantify the amount of translation enables researchers and clinicians alike to evaluate the effectiveness of various interventions for the restoration of AP laxity and, hence, measure success (Irrgang, 2008).

Although the clinical measures discussed provide valid and reliable methods to evaluate the extent and severity of knee impairment, a comprehensive assessment of disability also requires an understanding of functional limitations and participation restriction. Although it is conceivable that greater impairment results in greater functional limitation, the correlation between impairment and function is poorly supported within the literature. In a comparison of knee laxity and functional outcomes, Snyder-Mackler, Fitzgerald, Bartolozzi, and Ciccotti (1997) were unable to demonstrate a correlation when comparing 20 ACL deficient knees. Furthermore, Tyler, McHugh, Gleim, and Nicholas (1999) compared functional outcomes with STSD in anterior tibial displacement using the KT-1000 (n=90), drawing the same conclusion at one year post ACLR. It is, therefore, essential that
functional limitations are assessed independently using valid and reliable outcome measures to assist in accurately determining the level of disability (Arneja & Leith, 2009; Irrgang, 2008; Snyder-Mackler et al., 1997; Tyler et al., 1999).

2.2.3 Assessing functional limitations and participation restriction

As defined by the ICF, body functions are physiological functions of body systems (including psychological) (World Health Organisation, 2013). In the context of ACL rupture, the normal function of the knee is impaired, resulting in functional limitations [Figure 2-5]. In order to assess and quantify the level of dysfunction, a number of outcome measures have been developed and are described as either clinician assessed or patient reported (Irrgang, 2008; Khanna, Singh, Pomeroy, & Gioe, 2011; Pantano et al., 2001; Wang, Jones, Khair, & Miniaci, 2010).

Clinician assessed outcomes

With clinician-assessed functional outcomes, various limitations are reviewed or tested by the clinician in the form of observation, subjective assessment or more formally through objective outcome measures (Khanna et al., 2011; Risberg, Holm, Tjomsland, Ljunggren, & Ekeland, 1999; Sernert et al., 1999). There are a broad range of clinician-assessed outcome measures; however, the various hop tests are among the most widely reported due to their validity and reliability, ease of administration, functional relevance and cost effectiveness (de Jong, van Caspel, van Haeff, & Saris, 2007; Risberg, Holm, Tjomsland, et al., 1999; Sernert et al., 1999).

Single leg hop tests

The single leg hop test for distance (SLHD) was first described by Daniel et al. (1982); however, there are now a number of variations available that assess a range of functional limitations associated with ACL deficiency (Daniel et al., 1982; Daniel, Stone, Riehl, & Moore, 1988; Grindem et al., 2011; Gustavsson et al., 2006; Kramer, Nusca, Fowler, & Webster-Bogaert, 1992; Logerstedt et al., 2012). A single leg vertical jump, single leg triple hop for distance, cross over single leg hop for distance and timed six-metre single leg hop are some of the common variations (Gustavsson et al., 2006; Noyes, Barber, & Mangine, 1991).

Primarily due to the ease of administration, functional relevance and reliability, the SLHD is widely used (Engelen-van Melick, van Cingel, Tijssen, & Nijhuis-van der Sanden, 2013; Grindem et al., 2011; Gustavsson et al., 2006; Hopper, Strauss, Boyle, & Bell, 2008; Jang, Kim, Ha, Wang, &
During the test, the subject is instructed to stand on the limb to be tested with the arms free by their side and to jump as far forward as possible landing on the same limb. A successful attempt requires the person to maintain the landing for more than two seconds without the other limb touching the ground [Figure 2-10 A]. Three trials are attempted on the non-involved limb initially, followed by three trials on the involved limb with the mean distance of each limb calculated. The mean of the involved limb is divided by the mean of the non-involved limb and multiplied by 100 to give a limb symmetry index (LSI) where 85% or greater is considered to be normal (Daniel et al., 1982; Daniel et al., 1988; Gustavsson et al., 2006; Noyes et al., 1991; Reid et al., 2007; Wilk, Romaniello, Soscia, Arrigo, & Andrews, 1994).

Based on the principles of the SLHD protocol and LSI calculation, other variations have been developed to replicate the variety of movements that occur in normal activity. The single leg vertical jump is delivered in the same manner as the SLHD; however, the participant is positioned next to a wall and instructed to jump as high as possible, marking the wall with the fingertips to record the height reached (Barber, Noyes, Mangine, McCloskey, & Hartman, 1990). The timed single leg hop requires the participant to hop in a straight line for six metres as quickly as possible [Figure 2-10 B] (Barber et al., 1990). The single leg triple hop for distance requires the participant to consecutively hop three times in a straight line using the same limb to achieve the greatest distance [Figure 2-10 C] while the crossover hop requires the participant to cross from left to right of a line over the three consecutive jumps [Figure 2-10 D] (Noyes et al., 1991).
Table 2-3 summarises the sensitivity, specificity and reliability of the commonly reported hop tests among patients with ACL injury. All measures have reported an acceptable level of test-retest reliability; however, variability exists in the sensitivity and specificity. The SLHD, single leg vertical jump and the timed six-metre single leg hop test reported low to moderate sensitivity with moderate to high specificity, indicating an ability to accurately identify a normal limb when LSI is greater than 85%. Conversely, the single leg triple hop for distance and the single leg crossover hop for distance demonstrate moderate to high sensitivity and low specificity, representative of a greater ability to detect an abnormal limb when the LSI is less that 85% (Gustavsson et al., 2006; Logerstedt et al., 2012; Reid et al., 2007). Based on the identified differences, an increase in the accuracy of the various hop tests can be achieved by undertaking more than one hop test (Engelen-van Melick et al., 2013; Gustavsson et al., 2006).
Table 2-3: Sensitivity, specificity and reliability of single leg hop tests in ACLR

<table>
<thead>
<tr>
<th>Single leg hop test</th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
<th>ICC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single leg hop test for distance</td>
<td>63%</td>
<td>97%</td>
<td>0.92</td>
</tr>
<tr>
<td>Single leg vertical jump</td>
<td>67%</td>
<td>87%</td>
<td>0.97</td>
</tr>
<tr>
<td>Single leg triple hop for distance</td>
<td>77%</td>
<td>46%</td>
<td>0.88</td>
</tr>
<tr>
<td>Single leg crossover hop for distance</td>
<td>88%</td>
<td>47%</td>
<td>0.84</td>
</tr>
<tr>
<td>Timed 6m single leg hop</td>
<td>49%</td>
<td>94%</td>
<td>0.82</td>
</tr>
<tr>
<td>Single leg hop test for distance</td>
<td>63%</td>
<td>97%</td>
<td>0.92</td>
</tr>
</tbody>
</table>

ICC – Interclass correlation coefficient
Summarised from (Gustavsson et al., 2006), (Logerstedt et al., 2012) and (Reid et al., 2007)

Hop tests provide an accurate measure of muscle strength, dynamic control and limb confidence in a simple, easy to administer and cost effective manner. However, they are limited in their ability to address the other aspects of functional limitation and participation restriction associated with ACL injury. For this reason, there has been a trend towards assessing the patient’s perception of function and outcome (Johnson & Smith, 2001; Pantano et al., 2001; Wang et al., 2010). With a greater demand on patient specific outcomes and a lack of correlation between clinical testing and patient satisfaction, patient reported outcomes have emerged as a simple and cost effective method that allows the patient to quantify their level of impairment or function in relation to quality of life and satisfaction (Barenius, Forssblad, Engstrom, & Eriksson, 2013; Johnson & Smith, 2001; Roos, 2001; Tanner, Dainty, Marx, & Kirkley, 2007; Wright, 2009).

Patient reported outcome measures
The literature estimates that between 38 and 54 patient reported outcome measures are available for use in ACL injury (Johnson & Smith, 2001; Risberg, Holm, Steen, & Beynnon, 1999). However, a lack of rigor in the development and evaluation has seen the majority of these measures receive limited use (Johnson & Smith, 2001; Risberg, Holm, Steen, et al., 1999; Tanner et al., 2007; Wang et al., 2010; Wright, 2009). In contrast, the Lysholm Score, Tegner Score, Cincinnati Knee Rating System, International Knee Documentation Committee (IKDC) Subjective Knee Evaluation Form, and the Knee Injury and Osteoarthritis Outcome Score (KOOS) have all demonstrated the necessary psychometric properties to deliver a valid and reliable tool, reflected by their wide use throughout the ACL literature (Collins, Misra, Felson, Crossley, & Roos, 2011; Johnson & Smith, 2001; Neeb, Aufdemkampe, Wagener, & Mastenbroek, 1997; Risberg, Holm, Steen, et al., 1999; Sernert et al., 1999; Wang et al., 2010; Wright, 2009).
Lysholm Score

Recognised as the first adequately tested patient reported outcome measure, the Lysholm score has been widely used in the evaluation of ACL injury and intervention (Irrgang et al., 2001; Johnson & Smith, 2001; Risberg, Holm, Steen, et al., 1999; Wright, 2009). First published in 1982 by Lysholm and Gillquist and later modified in 1985 by Tegner and Lysholm, the Lysholm score is composed of eight scored items. Each item relates to a common impairment or functional limitation with a higher score assigned to items that are deemed to have a greater impact on outcome. For example, items referring to instability are scored between 0 and 25 points and items relating to gait are scored between 0 and 5 points. The aggregate score for each item is calculated with 100 being the maximum. Results are interpreted as excellent (95-100), good (84-94), fair (65-83) or poor (≤64) (Collins et al., 2011; Lysholm & Gillquist, 1982; Tegner & Lysholm, 1985). Although not officially reported, the estimated time to complete the questionnaire based on clinical experience is between five and 10 minutes and scoring can be completed in less than five minutes.

As part of the published modifications made to the Lysholm score in 1985, Tegner and Lysholm also introduced an activity scale, named the Tegner Activity Level, to complement the Lysholm score (Collins et al., 2011; Tegner & Lysholm, 1985). Based on the authors’ observations, a high Lysholm score could be masked by relatively low activity levels affecting the interpretation of results. The introduction of a scale that quantified activity levels pre and post injury allowed greater accuracy in interpreting the Lysholm score (Tegner & Lysholm, 1985).

Tegner Activity Level

The Tegner Activity Level instructs a person to rate their pre-injury and current level of activity on a numerical scale from 0 to 10 as represented by written descriptors. The graduated list starts at level 0 described as “sick leave or disability pension because of knee” and progresses to level 10 described as “Competitive sports – soccer, football, rugby (national elite)”. Results are interpreted based on the comparison of pre-injury level and post-injury level, providing context to the interpretation of the Lysholm score. The Test is simple and quick to administer and provides an objective level of function relative to pre-injury as reported by the patient (Tegner & Lysholm, 1985).

Cincinnati Knee Rating System

Soon after the initial Lysholm Score was published, Noyes, McGinniss, and Mooar (1984) published the Cincinnati Knee Rating System, a 100-point rating system divided into subjective (50
points) and functional (50 points). The subjective section is focused on impairment including items for pain (20 points), swelling (10 points) and giving way (20 points) while the functional section includes overall activity (20 points), walking (10 points), stairs (10 points), running (5 points) and jumping or twisting (5 points). Over time additional rating scales have been added to the rating system, including occupational activities scale (100 points), sports activity scale (100 points) and an overall rating scale (100 points) to produce a 13 scale rating system. The overall rating system incorporates patient reported factors with clinician-assessed factors such as knee ROM, knee laxity as measured by an instrumented device and radiographic information (Barber-Westin, Noyes, & McCloskey, 1999; Noyes, McGinniss, et al., 1984; Wright, 2009).

International Knee Documentation Committee Subjective Knee Evaluation Form

In response to an identified lack of consistency in knee reporting systems, limiting the ability to compare findings and conduct meta-analysis, the International Knee Documentation Committee undertook a rigorous process to develop a standardised patient reported outcome measure (Irrgang et al., 2001). The committee recognised the need to develop a tool with standard terminology that assessed knee motion and function with the vision of allowing cross comparison of surgical outcomes. Numerous evaluations were conducted between 1987 and 2000 at which time Irrgang et al. (2001) published the 2000 IKDC Subjective Knee Evaluation Form, divided into three domains including symptoms, sports and daily activities, and current and previous level of function, a total of 18 items are answered and scored. Upon completion of the test, a raw score is obtained by summing the scores from each item (excluding 10a) and converting to a percentile score as outlined below:

\[
\frac{(\text{Sum of items})}{(\text{Maximum possible score})} \times 100 = \text{IKDC percentile score}
\]

The score is relative to age and sex based norms and the possible score ranges from 0 to 100, where 0 is the inability to perform any daily activities and 100 is no limitation with daily or sporting activities. The test is freely available and easy to administer and takes approximately 10 minutes to complete plus 5 minutes to score (Collins et al., 2011; Irrgang et al., 2001; Wright, 2009).

Knee Injury and Osteoarthritis Outcome Score

Similar to the IKDC Subjective Knee Form, the Knee Injury and Osteoarthritis Outcome Score (KOOS) was developed as a self-administered patient reported outcome measure for assessing pain,
swelling, ROM, activities of daily living, function and knee related QoL (Roos, Roos, Lohmander, Ekdahl, & Beynnon, 1998). The KOOS was created as an extension to the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) to assess sporting injuries and outcomes in young to middle-aged athletes. The KOOS includes five domains with a total of 42 items all measured on a 5-point Likert scale, with the original 24 items of the WOMAC included in full. Each individual domain is scored as the sum of each item and reported as 5 individual scores. Scores for each domain are then transformed to a 0 to 100 scale as a percentage of the total score and interpreted as 0 being extreme knee problems and 100 as no problems at all. The KOOS is freely available and takes approximately 10 minutes to complete and 5 minutes to score (Collins et al., 2011; Roos et al., 1998).

**Psychometric properties of patient reported outcomes**

The patient reported outcome measures commonly used in the functional assessment of ACL injury have undergone extensive evaluation of their psychometric properties (Collins et al., 2011; Johnson & Smith, 2001; Neeb et al., 1997; Wang et al., 2010; Wright, 2009). A comprehensive review conducted by Wang et al. (2010) reported the validity, reliability and responsiveness for each of the outcome measures published between 1985 and 2010. Furthermore, Collins et al. (2011) conducted a similar review, supporting the findings of Wang et al. (2010). Table 2-4 summarises the psychometric properties of the measures discussed.

All measures demonstrated acceptable face validity with the relevant impairments and limitations associated with ACL injury. Additionally, all studies reported a level of convergent and divergent construct validity when correlated to measures assessing similar domains of impairment and function. The IKDC demonstrated the overall highest level of internal consistency and test-retest reliability compared to other measures. However, all measures demonstrated an acceptable level of reliability. The Cincinnati Knee Rating System demonstrated the highest level of responsiveness except on the activities of daily living scale. However, again, all measures generally demonstrated an effect size greater than 0.8, indicative of acceptable responsiveness.
<table>
<thead>
<tr>
<th>Outcome measures</th>
<th>Validity</th>
<th>Reliability</th>
<th>Responsiveness</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Lysholm</strong></td>
<td>Inclusion of relevant domains as assessed by 5 orthopaedic surgeons</td>
<td>Cronbach’s α: 0.65 – 0.73</td>
<td>ICC: 0.88 – 0.97</td>
</tr>
<tr>
<td></td>
<td>Correlated with Cincinnati, IKDC, WOMAC</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>ES (months): 1.1 (12-24m)</td>
</tr>
<tr>
<td><strong>Tegner</strong></td>
<td>Wide variety of activities included in scale developed by orthopaedic surgeons and patients</td>
<td>NA</td>
<td>0.82 – 0.92</td>
</tr>
<tr>
<td></td>
<td>Correlated with the IKDC, WOMAC, Oxford Knee Score</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>ES (months): 1.0 (12-24m)</td>
</tr>
<tr>
<td><strong>Cincinnati</strong></td>
<td>Inclusion of relevant domains and reported no or limited floor and ceiling effects</td>
<td>NA</td>
<td>0.84 (pain)</td>
</tr>
<tr>
<td></td>
<td>Correlated with IKDC, Lysholm, WOMAC</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.83-0.87 (symptom)</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>0.68-0.88 (ADL)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.85-0.98 (sport/rec)</td>
<td></td>
</tr>
<tr>
<td><strong>IKDC</strong></td>
<td>Covers the relevant domains of symptoms, function and sport activity</td>
<td>0.77 – 0.91</td>
<td>0.90 – 0.95</td>
</tr>
<tr>
<td></td>
<td>Correlated with Lysholm, Cincinnati, QoL for ACL deficiency and WOMAC</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>11.5 – 20.5</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(6-28m)</td>
<td></td>
</tr>
<tr>
<td><strong>KOOS</strong></td>
<td>Developed with expert panel, literature review and patient input</td>
<td>0.84-0.91 (pain)</td>
<td>0.85-0.93 (pain)</td>
</tr>
<tr>
<td></td>
<td>Correlated with SF-36, WOMAC and reports acceptable dimensionality</td>
<td>0.25-0.75 (symptom)</td>
<td>0.83-0.95 (Symptom)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.94-0.96 (ADL)</td>
<td>0.75-0.91 (ADL)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.85-0.89 (sport/rec)</td>
<td>0.61-0.89 (sport/rec)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.64-0.9 (QoL)</td>
<td>0.83-0.95 (QoL)</td>
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</table>

IKDC – International Knee Documentation Committee Subjective Knee Evaluation Form; WOMAC – Western Ontario and McMaster Universities Osteoarthritis Index; ICC – Interclass Correlation Coefficient; SEM – Standard Error of Measurement; MCID – Minimal Clinical Important Difference; ES – Effect Size; Cincinnati – Cincinnati Knee Rating System; QoL – Quality of Life; NR – Data not reported; Adapted from Collins et al. (2011) and Wang et al. (2010)
2.2.4 Implications of assessing disability in ACL injury

A comprehensive understanding of the various valid and reliable outcome measures available for ACL rupture enables the clinician to quantify disability. Through combining various measures, based on the aspects of health to which they relate, impairment, functional limitation and participation restriction can be accurately assessed to determine optimal treatment as well as evaluate the effectiveness of interventions. Furthermore, through the collection of objective data, participant outcomes can be compared, enabling research to be conducted to determine the efficacy of various interventions.

2.3 Management of anterior cruciate ligament injuries

In order to achieve a successful outcome in the management of an ACL deficient knee, it is vital that impairments are limited, function is maximised and activity levels restored. Intervention can be broadly categorised into two modes: (1) conservative (non-surgical) management and (2) surgical management. Both methods aim to achieve the common goal of restoring knee kinematics, returning a person to their previous level of function, minimising the risk of future injury and preventing the occurrence of long term degenerative changes.

Conservative management primarily involves active rehabilitation and where necessary the use of functional bracing to limit instability (Banovetz, Albright, & Crowley, 1997; Kessler et al., 2008). In the acute post injury phase, treatment focuses on the reduction of swelling and pain, restoration of normal ROM, resumption of independent mobility and limiting episodes of giving way (Strehl & Eggli, 2007; Zatterstrom, Friden, Lindstrand, & Moritz, 2000). Intervention progresses to muscular strengthening with primarily closed chain exercises, muscle co-contraction to minimise anterior tibial translation, neuromuscular retraining and proprioception based exercises (Strehl & Eggli, 2007; Zatterstrom et al., 2000). Once limb strength is approximately 80% of the uninjured side, the patient can progress to jogging, running, endurance as well as agility and perturbation training before progressing to sport specific activities, depending on individual patient goals (Fitzgerald, Axe, & Snyder-Mackler, 2000; Strehl & Eggli, 2007; Zatterstrom et al., 2000).

Surgical management aims to restore knee stability, biomechanics and function through replacement of the ACL. Surgery is generally performed arthroscopically with the patient positioned in supine, draped in the standard fashion, and the knee flexed to between 90 and 120
degrees. Two or three access portals are established, including an anterolateral and anteromedial plus or minus an accessory anteromedial portal (the anteromedial portal is proposed to improve anatomical positioning of the tibial tunnel but is dependent on surgical preference) (Chalmers, Mall, Yanke, & Bach, 2013; Martins, Kropf, Shen, van Eck, & Fu, 2008; van Eck et al., 2010). Depending on graft choice, a longitudinal or horizontal incision is made in the respective location to allow harvesting of the graft. The graft is then prepared and a tibial and femoral tunnel established to insert the graft. Once inserted, the graft is tensioned and fixed at the femur and tibia relevant to the surgical method chosen (Andersson, Samuelsson, & Karlsson, 2009; Arciero et al., 1996; Beynnon, Johnson, Abate, Fleming, & Nichols, 2005; Chalmers et al., 2013; Middleton et al., 2014; van Eck et al., 2010; Voigt, Schönaich, & Lill, 2006).

2.3.1 Conservative versus surgical management

Outcomes achieved through a conservative approach have been varied within the literature. Muaidi, Nicholson, Refshauge, Herbert, and Maher (2007) undertook a systematic review with meta-analysis of 15 studies, evaluating short and mid-term outcomes of conservative management post ACL rupture. Based on pooled analysis, the mean (95% CI) outcomes were Lysholm score 87 (83 – 92), Tegner Activity Score 5.6 (5.3 – 5.6) and SLHD LSI of 96% (93 – 98). These findings were indicative of an acceptable functional outcome based on the measures used. Long-term studies of conservative management have also reported positive results, with studies demonstrating that non-operative approaches have similar long-term functional outcomes and potentially lower rates of osteoarthritis when compared to surgical management (Fitzgerald et al., 2000; Kessler et al., 2008; Meuffels et al., 2009; Meunier et al., 2007; Moksnes & Risberg, 2009). In contrast, some literature reports that conservatively managed ACL injuries present with increased joint laxity, a greater risk of meniscal damage post injury and reduced long-term activity levels (Meuffels et al., 2009; Mihelic, Jurdana, Jotanovic, Madjarevic, & Tudor, 2011; Strehl & Eggli, 2007) while surgically managed patients subjectively perceive a better outcome and maintain higher levels of sports participation (Fink, Hoser, Hackl, Navarro, & Benedetto, 2001).

There is uncertainty about whether conservative or surgical management provides the optimal outcome post ACL rupture. Smith, Postle, Penny, McNamara, and Mann (2014) undertook meta-analysis of 16 studies comparing conservative and surgical management, reporting conservatively managed patients had significantly less incidence of impaired ROM in the mid-term (flexion p=0.02; extension p=0.004) and reduced likelihood of developing osteoarthritis in the long-term (p=0.05) while surgical intervention resulted in significantly less STSD in anterior tibial
displacement in both the mid and long-term (p=0.003; p=0.001, respectively). However, of the 16 studies included in the meta-analysis, the methodological quality was poor based on the PeDro critical appraisal tool (Moseley, Herbert, Sherrington, & Maher, 2002), with only one study including random allocation and two studies including blinded assessors.

Although there is an argument that conservative management can provide similar outcomes to surgical management, the number of conservatively managed patients requiring subsequent surgery must be considered. Strehl and Eggli (2007) reported 63% of conservatively managed patients required surgery by 13.3 months post rupture, concluding only one-third of patients succeed with conservative intervention. Although the study conducted by Strehl and Eggli (2007) was non-randomised with a small sample (n=38), the findings were later supported by a prospective randomised controlled trial (n=121) conducted by Frobell et al. (2013). This study found that 51% of participants undergoing conservative management required surgical intervention within 5 years, secondary to recurrent symptoms and functional limitations (Frobell et al., 2013).

With an observed trend that a sub-group of patients fail with conservative management, it is accepted that ACL deficient knees will respond differently (Button, van Deursen, & Price, 2006). In response, terms such as ‘coper’, ‘non-coper’ and ‘adaptor’ have emerged in the literature to describe an individual’s response to ACL deficiency (Button et al., 2006). Based on the literature, a ‘coper’ will return to their previous level of function without reconstruction of the ACL; an ‘adaptor’ will successfully modify their daily activity and function with an ACL deficient knee and the ‘non-coper’ will unsuccessfully manage daily function and will subsequently require surgical reconstruction of the ACL (Eastlack, Axe, & Snyder-Mackler, 1999; Fitzgerald et al., 2000; Herrington & Fowler, 2006; Moksnes & Risberg, 2009; Rudolph, Axe, & Snyder-Mackler, 2000). Unfortunately, there is no evidence based guide that clearly outlines who will cope and who will not. Factors such as higher previous level of activity, younger age group, greater amount of laxity, presence of functional instability, severity of injury, patient decision and gender have been reported to influence outcome; however, there has been no clear evidence to support this (Daniel et al., 1994; Fithian et al., 2005; Kapoor, Clement, Kirkley, & Maffulli, 2004; Mirza, Mai, Kirkley, Fowler, & Amendola, 2000).

In the absence of clear evidence to predict optimal intervention post ACL rupture, the decision for treatment ultimately lies with the individual in collaboration with their health care provider. Recent surgical trends show that more people are electing surgical intervention with procedures increasing 58.9% between 1998 and 2008 in Australia (Orchard, 2009), which is similar to that reported by the
Swedish National Knee Ligament Register (59.8% between 2005 and 2013) (The Swedish national knee ligament register, 2013; The Swedish national knee ligament registry, 2010, 2011, 2012). Furthermore, an estimated 60.3% of all ACL deficient patients elect to undergo surgery (The Swedish national knee ligament register, 2013). Although the reason behind such an increase is unclear, the fact remains that a greater number of people are electing to undergo surgical intervention, indicating the importance of surgery in the management of the ACL deficient knee.

2.3.2 Surgical management of ACL injury

Historical perspectives
Historically, surgical interventions (early 1900’s) primarily focused on open repair using various suturing techniques (Schindler, 2012). However, due to the presence of ligament tethering and the proximity of most ruptures to the femur, suture fixation often failed, leading to poor surgical outcomes (Schindler, 2012). Although the process of repairing the ACL continued into the 1970’s, the body of evidence criticising the long-term outcome and the advancement of alternative surgical reconstruction methods confirmed its ineffectiveness as a valid treatment for ACLR (Chalmers et al., 2013; Schindler, 2012).

Ligament reconstruction surpassed the previously advocated surgical repair due to its superior outcomes. The first documented reconstruction was performed by Ernest William Hey Groves at the Bristol General Hospital in 1917 and involved detachment of the fascia lata (ilio-tibial band) from the tibia before passing through a femoral and tibial tunnel and attaching it to the periosteum of the tibia (Groves, 1917; Schindler, 2012). Although a landmark procedure, surgical reconstruction of the ACL remained controversial and debated right into the 1970’s with conservative management the preferred method. However, refinement of the reconstructive methods and the development of new surgical techniques, such as arthroscopy, have led to the modern ACLR (Dandy, 1982; Schindler, 2012).

An arthroscopic approach to ACL reconstruction is universally accepted as the primary method due to the reduction in surgical trauma and post-operative morbidity, greater visualisation and superior accuracy for tunnel placement (Chalmers et al., 2013; Dandy, 1982; Martins et al., 2008; Middleton et al., 2014; Raab, Fischer, Smith, Markman, & Steubs, 1993; van Eck et al., 2010; Woo et al., 2006). Initially, in the mid 1980’s, a 2-incision technique was preferred where the tibial and femoral tunnels were drilled independently via separate incisions. However, in the 1990’s the 1-incision
technique (also termed the trans-tibial technique) was developed, allowing the femoral tunnel to be drilled via the tibial tunnel. Although technically difficult, the 1-incision method further reduced surgical trauma and post-surgical morbidity and is the most common procedure reported in the current literature (Arciero et al., 1996; Chalmers et al., 2013; van Eck et al., 2010).

Although the surgical process for ACLR has evolved over the last century, clinicians continue to refine and develop the procedure to improve patient outcomes. With an aim to replicate the native ACL, four surgical processes can be manipulated in order to achieve an anatomical ACLR, including: (1) the selection of an appropriate graft, (2) the drilling of appropriately placed tibial and femoral tunnels, (3) fixation of the graft at the femur and tibia, and (4) the application of adequate graft tension (Chalmers et al., 2013; Raab et al., 1993; van Eck et al., 2010; Woo et al., 2006).

**Graft selection**

Arguably, graft choice is the most crucial decision in terms of achieving a successful outcome. For this reason, there is a plethora of published literature comparing the various grafts and the outcomes achieved post surgery. Based on the current literature there are three primary grafts commonly used for ACLR: (1) bone patella tendon bone (BPTB), (2) semitendinosus gracilis (STG), and (3) synthetic grafts (Chalmers et al., 2013; Middleton et al., 2014; Mohtadi, 1998; Reinhardt, Hetsroni, & Marx, 2010; Sajovic et al., 2011; Voigt et al., 2006). In the case of the BPTB and STG, the graft can be autograft (harvested from the patient) or allograft (harvested from cadaver), and in the STG, the surgeon can create a single or double bundle graft.

Although making a recent resurgence with improved biomaterials, the use of synthetic grafts is still limited. The poor long-term outcomes from the 1980’s and limited long-term evidence for current generation synthetic ligaments has resulted in scepticism in the use of these grafts (Mulford & Chen, 2011; Parchi et al., 2013). In contrast, there is a large body of long-term evidence supporting the use of BPTB and STG grafts, explaining why these are the most commonly utilised and considered the current gold standard (Barber, Cowden, & Sanders, 2014; Holm, Oiestad, Risberg, & Aune, 2010; Mohtadi, Chan, Dainty, & Whelan, 2011; Pinczewski, Deehan, Salmon, Russell, & Clingeleffer, 2002).

Despite a consensus on the use of either the BPTB or STG graft, there is some debate as to whether allograft or autograft provides a better outcome (Greenberg, Robertson, Vallurupalli, White, & Allen, 2010). Allografts offer the advantage of eliminating donor-site morbidity, allowing predictable graft sizes, reduction in operation time and early rehabilitation (Foster, Wolfe, Ryan,
Silvestri, & Kaye, 2010; Greenberg et al., 2010). However, the proposed risks of disease transmission and immunological response as well as the reported slower graft incorporation, limitations with availability, cost and potential increased failure rate have seen the autograft more widely accepted as current practice in ACLR (Barber et al., 2014; Foster et al., 2010; Greenberg et al., 2010; Maletis, Inacio, Desmond, & Funahashi, 2013; Maletis, Inacio, Reynolds, et al., 2013; Rahr-Wagner, Thillemann, Pedersen, & Lind, 2014).

Comparison of BPTB and STG autograft outcomes are widely publicised with numerous long-term prospective randomised trials, systematic reviews and meta-analysis. Pinczewski et al. (2002) published a comprehensive and well cited paper comparing 5-year outcomes between the BPTB and STG autograft, reporting that the BPTB autograft resulted in significantly less STSD in anterior tibial displacement as measured by the KT-1000 but significantly greater pain and disability associated with kneeling. There were no significant differences in all other measures including symptoms, ROM, patient reported function, single leg hop test or patient satisfaction, leading the authors to conclude that both methods are successful in restoring stability and function post ACL rupture (Pinczewski et al., 2002). More recently, Mohtadi et al. (2011) conducted a Cochrane review, comparing outcomes for BPTB and STG autograft. Nineteen studies were included in the review, which reported significantly less anterior laxity but significantly greater anterior knee pain with the BPTB autograft while all other outcomes were equal between the two grafts (Mohtadi et al., 2011). The most recent evidence emerging from population-based studies suggests that STG autograft failure rate is higher when compared to BPTB autograft (Persson et al., 2014; Rahr-Wagner et al., 2014). Although both groups have relatively low overall revision rates, the STG autograft is 2.3 – 3.6 times more likely to fail in the first year post surgery when compared to BPTB autograft (Persson et al., 2014; Rahr-Wagner et al., 2014). However, with the high reported success rates evident in both methods in terms of restoring stability and function, both the STG or BPTB autografts are considered acceptable choices for the reconstruction of the ACL.

In the case of the STG autograft, a further delineation can be drawn with the potential for either a single or double bundle method (Branch, Siebold, Freedberg, & Jacobs, 2011; Chalmers et al., 2013; Gadikota et al., 2010; Jarvela, 2007; Lewis et al., 2008; van Eck et al., 2010). Although the proposition of a double bundle method has been around since the 1930’s, the technique has become more popular in recent years with advancements in surgical methodology and the suggestion that it more closely resembles the native ACL; hence improving patient outcomes (Chalmers et al., 2013; Gadikota et al., 2010; Karlsson et al., 2011; Park et al., 2010; Schindler, 2012; van Eck et al., 2010). Although there is a growing body of literature discussing the double bundle method, the technical
challenges and greater potential for complications associated with the procedure have limited its wide acceptance. For this reason, the single bundle method is currently the most commonly performed procedure and supported as an acceptable method within the literature (Karlsson et al., 2011; Lewis et al., 2008).

Tunnel placement
Positioning of the tibial and femoral tunnels will dictate graft position and length and is therefore, pivotal to a successful outcome. A poorly placed tunnel will result in greater laxity, graft impingement, loss of ROM, undue graft tension through ROM, greater risk of graft failure and poorer clinical outcomes for the patient (Beynnon et al., 2005; Fu & Karlsson, 2010; Karlsson et al., 2011). Correct placement of the tunnel is complex, with consideration of three-dimensional positioning across the tibial and femoral tunnels fundamental to success. The aim of an ideal tunnel position is to avoid posterior cruciate ligament (PCL) impingement and ensure normal flexion, avoid roof impingement to restore normal extension and match the native ACL tension pattern to restore biomechanics (Howell & Hull, 2009). Although it is not clear exactly what the perfect tunnel position is, aiming for an anatomically placed tunnel to anchor the graft in a position that best replicates the native ACL is considered the gold standard (Cross et al., 2012; Fu & Karlsson, 2010; Karlsson et al., 2011; van Eck et al., 2010).

In the case of the commonly used trans-tibial technique, the angle of the tibial tunnel is critical as it guides femoral tunnel placement. Studies by Howell and Hull (2009), Silva, Sampaio, and Pinto (2010) and Simmons, Howell, and Hull (2003), have all concluded that a tibial tunnel positioned at 60–65 degrees in the coronal plane [Figure 2-11 A] minimises risk of PCL impingement, reduces graft tension in high flexion, improves ability to position the femoral tunnel in the anatomical footprint and reduces laxity. In the sagittal plane, the anterior edge of the tibial tunnel should lie just posterior and parallel to the slope of the inter-condylar roof when the knee is in full extension to avoid roof impingement [Figure 2-11 B] (Howell, Gittins, Gottlieb, Traina, & Zoellner, 2001; Howell & Hull, 2009).

Femoral tunnel angle is commonly referenced in terms of a clock face to describe the angle in the coronal plane where 12 o’clock represents a vertical position and 9 o’clock or 3 o’clock represent a horizontal position for the right and left knees respectively [Figure 2-11 B]. Ideal femoral tunnel angle is suggested to fall between 10:00 and 10:30 on the right or 1:00 and 1:30 on the left. Jepsen, Lundberg-Jensen, and Faunoe (2007), Yamamoto et al. (2004) and Loh et al. (2003) all concluded that a femoral tunnel placed at a lateral angle of 10 o’clock or 2 o’clock more effectively restored
rotatory stability, compared to the vertical position of 11 o’clock or 1 o’clock. Similarly, Simmons et al. (2003) demonstrated that tension on the graft significantly increased through flexion as the tunnel angle approached a more vertical position i.e. closer to 12 o’clock.

**Figure 2-11: Tibial and femoral tunnel placement in ACLR**

In addition to the angle of the tunnel, placement of the tunnel in the footprint of the ACL is equally important. Based on the hypothesis that tension on the graft during knee motion would result in graft lengthening over time, position of the tunnels historically aimed for an isometric position (Chalmers et al., 2013; Schindler, 2012). Located at 2 points in the footprint of the ACL, as measured by a tensiometer, an isometric positioned tunnel remained equidistance apart through range, minimising graft strain through ROM (Chalmers et al., 2013; Schindler, 2012). However, with a growing body of research it is now understood that the native ACL is not isometric and long-term evaluation of ACLR using isometric tunnel placement suggests normal kinematics are not restored (Chalmers et al., 2013; Cross et al., 2012; Fu & Karlsson, 2010; Karlsson et al., 2011). This has prompted a shift to an anatomical (non-isometric) tunnel placement, which involves drilling the tibial and femoral tunnels in a position as close to the anatomical footprint of the native ACL (Cross et al., 2012; Karlsson et al., 2011; Schindler, 2012). Although anatomic graft placement is widely practised, there is still controversy as to what constitutes normal anatomic position (Chalmers et al., 2013; Cross et al., 2012; Fu & Karlsson, 2010; Karlsson et al., 2011). As discussed earlier, the
native ACL has a broad tibial and femoral footprint compared to the average single bundle ACL graft (approximately 9mm in diameter), which accounts for only 33% of the native ACL footprint. As a result, the surgeon is required to decide at which part of the footprint to locate the tunnel, which may vary from surgeon to surgeon (Cross et al., 2012; Karlsson et al., 2011; Schindler, 2012). Recent studies have postulated that a femoral tunnel placed centrally between the anteromedial and posterolateral footprint is best for restoring anterior and rotational stability in a single bundle ACLR using BPTB or STG autograft (Cross et al., 2012; Silva et al., 2010). However, based on the recency of evidence, there is no long-term data to determine if a graft placed anatomically in the centre of the AM and PL bundles improves long-term function or reduces the risk of OA when compared to other tunnel placements.

In summary, based on the available literature, a tibial tunnel positioned at a coronal angle of 60 – 65 degrees (Howell & Hull, 2009; Silva et al., 2010; Simmons et al., 2003) with a sagittal position just posterior and parallel to the slope of the inter-condylar roof (Howell & Hull, 2009), coupled with a femoral tunnel positioned at ten or two o’clock in the coronal plane (Jepsen et al., 2007; Loh et al., 2003; Yamamoto et al., 2004) and positioned in the centre of the AM and PL ACL footprint (Cross et al., 2012; Silva et al., 2010), has been shown to results in a successful long-term outcome post ACLR when using a trans-tibial technique.

**Graft fixation**

Graft fixation acts as the primary graft stabiliser, providing stiffness to the graft construct and facilitating the incorporation of the graft into the bone tunnel (Beynnon et al., 2005; Chalmers et al., 2013; Hapa & Barber, 2009; Harvey, Thomas, & Amis, 2005; Schindler, 2012; van Eck et al., 2010). An effective fixation method must minimise tunnel widening while providing adequate strength to allow early knee ROM, early weight bearing and enabling the commencement of rehabilitation (Brand, Weiler, Caborn, Brown, & Johnson, 2000; Hapa & Barber, 2009; Harvey et al., 2005). The two methods available are direct fixation (the device directly compresses the graft against the bone e.g. interference screw) or indirect fixation (where the graft is suspended within the bone tunnel e.g. cortical suspension devices). Selection is dependent on graft type, bone density, the fixation site and surgeon preference (Brand et al., 2000; Hapa & Barber, 2009; Harvey et al., 2005).

Direct fixation of the BPTB and STG autografts with a metal or bioabsorbable interference screw has demonstrated excellent long-term outcomes in ACLR in both the tibial and femoral tunnels (Gorschewsky, Stapf, Geiser, Geitner, & Neumann, 2007; Hapa & Barber, 2009; Harvey et al., 2005). The combination of sufficient strength and stiffness, ability to limit slippage and ease of
insertion has seen the interference screw widely used (Gorschewsky et al., 2007; Hapa & Barber, 2009; Harvey et al., 2005). Laupattarakasem, Laopaiboon, Kosuwon, and Laupattarakasem (2014), Drogset et al. (2010) and Gorschewsky et al. (2007) all reported satisfactory functional outcomes using an interference screw. Although the meta-analysis by Laupattarakasem et al. (2014) suggested that a bioabsorbable screw may result in greater tunnel widening compared with the metal screw. Indirect fixation with a cortical suspension device offers an alternative to the use of interference screws for soft tissue femoral fixation. Plaweski, Rossi, and Merloz (2009) demonstrated very good clinical results two years post surgery using the Endobutton Continuous Loop® (Smith & Nephew Inc, Andover Massachusetts) based on the IKDC, Lysholm, return to activity and laxity measurements, all of which were comparable to the interference screw. The evidence supports the use of both fixation devices for graft fixation in ACLR with successful outcomes demonstrated by both methods.

**Graft tension**

Prior to tibial fixation, graft tension is the final key factor for successful surgical reconstruction of the ACL. Application of optimal tension assists in the restoration of normal AP stability, restoration of normal knee kinematics and promotion of graft revascularisation and healing (Nicholas et al., 2004; Yoshiya, Kurosaka, Ouchi, Kuroda, & Mizuno, 2002). Insufficient tension will fail to restore stability and function while excessive tension will limit ROM, increase tissue strain, increase compressive joint forces, contribute to the failure of fixation method and increase the risk of graft failure (Fleming et al., 2013; Kim et al., 2006; Nicholas et al., 2004; Yasuda et al., 1997).

The application of tension requires the surgeon to apply a force to the graft that aids in the restoration of knee kinematics. Tension can be applied manually, which requires the surgeon to pull on the sutures attached to the femorally fixed graft by hand. The force is estimated by the surgeon and is commonly described as a sustained maximum one-handed pull. The manual method of tensioning is a clinically accepted approach and has demonstrated effective clinical outcomes in ACL surgery (Lewis et al., 2008). However, laboratory based studies by O'Neill et al. (2011) and Cunningham, West, Greis, and Burks (2002) have shown a lack of inter and intra-tester reliability with such a method indicating a level of variability in the tension applied, which may impact on outcomes. An alternative method involves the application of tension using a tensioning device (TD), which has been proposed to address such limitations and allow reliable and reproducible amounts of tension to be applied. Hypothesised to improve patient outcomes, the use of a tensioning device purportedly allows a precise tension to be applied to the relevant strands of the graft to
deliver a consistent and, thus, better patient outcome [Figure 2-12]. However, in order to deliver a better outcome, an understanding of what constitutes an optimal amount of tension is necessary.

**Figure 2-12: Tensioning with a tensioning device**

Controlled laboratory, cadaver and computer modelled methodologies have attempted to provide evidence for an optimal graft tension. Table 2-5 provides a comprehensive summary of the available literature investigating graft tensioning, which outlines various recommendations for the ideal amount of tension necessary to restore normal ROM, tibiofemoral (TF) compressive forces, graft remodelling and vascularity. Based on the studies reported, tensions ranging from 1N – 89N have been suggested to restore various aspects of normal knee biomechanics. Brady et al. (2007) reported that 1N – 15N applied between 0 and 20 degrees of knee flexion using a BPTB graft was most effective at restoring TF compressive forces while minimising the risk of tibial rotation or posterior translation. Similarly, an earlier study by Burks and Leland (1988) concluded that 16N of tension applied at 20 – 25 degrees of knee flexion was effective for restoring knee stability using a BPTB graft. In contrast, Austin, Phornphutkul, and Wojtys (2007) found that 89N of tension applied at full knee extension was most effective at restoring knee ROM and Gertel, Lew, Lewis, Stewart, and Hunter (1993) found that 67N applied at full extension effectively restored knee stability when using the BPTB graft. In studies investigating the STG grafts, Mae et al. (2008a)
found a tension of 44N applied at 20 degrees restored TF compressive forces and ROM, compared to Boylan et al. (2003) who concluded that 68N applied at 30 degrees knee flexion best restored knee stability.

Descriptive analysis of the studies presented in Table 2-5 report that a mean (SD) tension of 44.6(26.2)N, applied at 4.8(7.5) degrees, when using a BPTB autograft is effective in restoring AP laxity and ROM. In comparison, a mean tension of 60.6(14.4)N, applied at 20.3(9.5) degrees, when using the STG autograft was reported to effectively restore AP stability and knee ROM post ACLR. In contrast, studies investigating TF compressive force recommend a tension of 15N applied between 0 and 20 degrees using a BPTB autograft and 44N applied at 20 degrees for the STG autograft. Furthermore, a tension between 20N and 40N applied between 0 and 20 degrees was considered effective in minimising excessive graft strain and promoting graft remodelling.
<table>
<thead>
<tr>
<th>Study</th>
<th>Study design</th>
<th>Tension(s) (N)</th>
<th>Knee angle(s) (degrees)</th>
<th>Graft choice</th>
<th>Outcome</th>
<th>Recommended tensioning protocol</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bylski-Austrow, Grood, Hefzy, Holden, and</td>
<td>Cadaver</td>
<td>22N 44N</td>
<td>0 and 30</td>
<td>Simulated graft</td>
<td>Restoration of knee stability</td>
<td>44N applied at full extension using BPTB</td>
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<tr>
<td>Butler (1990)</td>
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<tr>
<td>Gertel et al. (1993)</td>
<td>Cadaver</td>
<td>22N 67N</td>
<td>0 and 30</td>
<td>BPTB</td>
<td>Restoration of knee stability</td>
<td>67N applied at 0 degrees using BPTB</td>
</tr>
<tr>
<td>Nabors, Richmond, Vannah, and McConville</td>
<td>Clinical trial and Cadaver</td>
<td>Clinical: MM 1-handed pull measured in vitro between 107N and 138N Cadaver: 68N</td>
<td>0</td>
<td>BPTB</td>
<td>Reduced risk of extension loss &gt;3 degrees Restoration of knee stability</td>
<td>Manually tensioning (mean 68N) in full extension using BPTB</td>
</tr>
<tr>
<td>Study</td>
<td>Study design</td>
<td>Tension(s) (N)</td>
<td>Knee angle(s) (degrees)</td>
<td>Graft choice</td>
<td>Outcome</td>
<td>Recommended tensioning protocol</td>
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<tr>
<td>Boylan et al. (2003)</td>
<td>Cadaver</td>
<td>23N 45N 68N</td>
<td>30</td>
<td>STG</td>
<td>Restoration of knee stability within 3mm</td>
<td>68N applied at 30 degrees flexion using STG</td>
</tr>
<tr>
<td>Study</td>
<td>Study design</td>
<td>Tension(s) (N)</td>
<td>Knee angle(s) (degrees)</td>
<td>Graft choice</td>
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<tr>
<td>Pena, Martinez, Calvo,</td>
<td>Finite element model</td>
<td>0N</td>
<td>0</td>
<td>BPTB</td>
<td>Restoration of knee stability</td>
<td>60N applied at full extension using BPTB</td>
</tr>
<tr>
<td>Palanca, and Doblare (2005)</td>
<td></td>
<td>20N</td>
<td>30</td>
<td>STG</td>
<td>Normal ROM</td>
<td>40N applied at full extension using BPTB</td>
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<td></td>
<td></td>
<td>40N</td>
<td>60</td>
<td></td>
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<td>60N</td>
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<td>Austin et al. (2007)</td>
<td>Cadaver</td>
<td>44N</td>
<td>0</td>
<td>BPTB</td>
<td>Restoring normal knee extension</td>
<td>44N applied at full extension using BPTB</td>
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<td></td>
<td></td>
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<td>30</td>
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<td>89N applied at full extension using BPTB</td>
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<tr>
<td>Brady et al. (2007)</td>
<td>Cadaver</td>
<td>1N</td>
<td>0</td>
<td>BPTB</td>
<td>TF compressive force</td>
<td>1N-15N applied at 0-20 degrees flexion using BPTB</td>
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<td></td>
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<td>15N</td>
<td>20</td>
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<td>30N</td>
<td>90</td>
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<td>60N</td>
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<td></td>
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<td>90N</td>
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<td>Study</td>
<td>Study design</td>
<td>Tension(s) (N)</td>
<td>Knee angle(s) (degrees)</td>
<td>Graft choice</td>
<td>Outcome</td>
<td>Recommended tensioning protocol</td>
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<tr>
<td>Mae et al. (2008b)</td>
<td>Cadaver</td>
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<td>0</td>
<td>STG</td>
<td>Normal knee ROM</td>
<td>44N applied at 20 degrees using STG</td>
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<tr>
<td></td>
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<td>20</td>
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<td>TF compressive forces</td>
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<td>90</td>
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<tr>
<td>Fleming et al. (2008)</td>
<td>Cadaver</td>
<td>25N</td>
<td>0</td>
<td>BPTB</td>
<td>TF compressive forces</td>
<td>Tension to -2mm AP laxity at full extension using BPTB to restore laxity</td>
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<tr>
<td></td>
<td></td>
<td>50N</td>
<td>30</td>
<td>BPTB</td>
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<td>Restoration of knee</td>
<td>STG</td>
<td>stability</td>
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<td></td>
<td></td>
<td>ROM</td>
<td></td>
<td>Normal knee ROM</td>
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<tr>
<td>Fleming et al. (2013)</td>
<td>Clinical trial</td>
<td>Restore normal laxity</td>
<td>0</td>
<td>BPTB</td>
<td>Restoration of knee stability</td>
<td>Tension to restore normal laxity at 30 degrees flexion using BPTB or STG</td>
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<td></td>
<td></td>
<td>-2mm AP laxity</td>
<td>30</td>
<td>STG</td>
<td>Patient function</td>
<td>Tension to over constrain knee by 2mm at full extension using BPTB or STG</td>
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<td></td>
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<td></td>
<td>QoL scores</td>
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</tbody>
</table>

BPTB – Bone patella tendon bone, STG – Semitendinosus gracilis, QoL – Quality of life, TF – Tibio-femoral, ROM – Range of motion
Although the studies presented in Table 2-5 provide some evidence for graft tensioning, none of the studies are clinical trials and there are a variety of recommendations based on competing points of view such as restoring stability versus TF compressive forces. Furthermore, the translation of such findings into patient outcomes is unclear and speculative. Limitations including the inability to extrapolate measures of laxity to patient function, the impact of freezing ligamentous tissue on its biological properties and the relationship between temperature and viscoelasticity make the extrapolation of cadaver findings to clinical outcomes difficult.

In 1998, Amis and Jakob published a report documenting the clinical recommendations for graft tensioning based on expert opinion collected at the second European Society of Sports Traumatology, Knee Surgery and Arthroscopy (ESSKA) congress. The topic of graft tensioning evoked much controversy and highlighted variations in clinical practice. The approach identified for graft tensioning, based on the typical practice of attendees at the congress, was 47N or 70N at 11 degrees of knee flexion using the BPTB or STG autograft respectively (Amis & Jakob, 1998).

In the absence of clear clinical evidence to guide graft tensioning and a wide variation in clinical practice, this thesis presents three studies to determine the effect of graft tensioning on patient outcomes post ACLR. Study one is a systematic review and critical appraisal of the literature to investigate the optimal tension for restoration of patient outcomes post ACLR (Chapter 3). Study two is a randomised controlled trial comparing two tensioning protocols on patient outcomes post ACLR (Chapter 4). Study three is a survey of orthopaedic surgeons to determine current clinical practice in graft tensioning and to identify which factors influence clinical practice (Chapter 5 and 6).
3 Initial graft tension and the effect on post-operative patient functional outcomes in anterior cruciate ligament reconstruction

As presented in the previous chapter, graft tensioning is critical to success in ACLR. A key component of the tensioning process is the amount of force applied, which is hypothesised to contribute to the restoration of knee stability, normal biomechanics and graft revascularisation. The aim of this chapter is to systematically review the current evidence to determine what is the optimal tension for restoring patient function post ACLR.

The chapter is adapted with minor additions and alterations to formatting to maintain the consistency of the thesis from the following publication:

3.1 Abstract

Purpose
The aim of this review was to investigate the effect of initial graft tension on patient-specific functional outcomes post anterior cruciate ligament reconstruction and determine if a particular tension is associated with superior functional outcome.

Methods
We performed a systematic review of prospective randomised trials with an NHMRC level of evidence of III or higher published between 1950 and July 2012. Articles utilizing a semitendinosus-gracilis or bone patella tendon bone autograft that reported graft tension and postsurgical functional outcomes were included in the study. Quantitative analysis was performed on available data by calculating Effect Size (ES) both at various time points and across tensions (N).

Results
Initial search strategies returned 457 original publications of which five articles fulfilled all exclusion and inclusion criteria. The mean (SD) for quality was 5.8 (1.3) with 12 being the highest possible score. 80N and 78.9N of tension recorded the largest effect at ≤2 weeks (ES = -2.98 (range -3.82, -2.14)); and ≥12 months (ES = -2.45 (range -3.40, -1.51)) post operatively, respectively, when compared to pre-operative side-to-side difference in anterior tibial displacement. When comparing tensions, the largest effect was towards 80N when compared to 20N at ≤2 weeks post surgery (ES = 0.76 (range 0.17, 1.35).

Conclusion
The objective of this review was to systematically assess the literature to determine if a particular initial graft tension results in superior outcomes post ACLR. From the review, there is a trend towards an initial graft tension of 78.5N – 90N, resulting in a reduced STSD in anterior laxity as measured by an instrumented knee laxity device. However, there is insufficient evidence to conclude whether patient-specific function is improved at any specific tension.

Clinical Relevance
This systematic review of randomised controlled trials has clinical relevance for surgeons to make an evidence based decision on the amount of tension required to produce an improved functional outcome for the patient.
3.2 Introduction

Restoration of normal knee kinematics through replicating the natural anterior cruciate ligament is core to achieving optimal outcomes in anterior cruciate ligament reconstruction (ACLR) (Andersen & Amis, 1994; Cunningham et al., 2002; Dargel et al., 2007; Woo et al., 2006). A number of factors have been proposed to contribute to such outcomes including graft choice, tunnel placement, graft tension, graft fixation, tunnel motion, graft healing and post-operative rehabilitation (Arneja et al., 2009; Ekdahl, Wang, Ronga, & Fu, 2008; Nicholas et al., 2004; Woo et al., 2006). Despite graft tension being recognized as a significant contributor to successful ACLR, there is little consensus on the amount of tension required to produce an optimal outcome (Arneja et al., 2009; Heis & Paulos, 2002). As a result, many surgeons rely on achieving an observed isometric graft prior to fixation to guide the amount of tension applied (Friederich & Verdonk, 2008).

Historically, graft tension was described subjectively as ‘strong tension’ or ‘as far as it would go’, and objectively as preservation of 5mm anterior-posterior translation (Clancy, Nelson, Reider, & Narechania, 1982; Noyes, Butler, Paulos, & Grood, 1983; Zarins & Rowe, 1986). In recent years, attempts have been made to quantify graft tension with the introduction of tensioning devices (Nicholas et al., 2004; van Kampen et al., 1998; Yasuda et al., 1997; Yoshiya et al., 2002). The quantifying of graft tension has been proposed to result in an optimal biomechanical outcome as well as an ideal environment for graft healing and ligamentization (Friederich & O’Brien, 1998; Heis & Paulos, 2002; Tohyama & Yasuda, 1998). Early investigation into the amount of tension a surgeon applies when manually tensioning a graft demonstrated significant variability between surgeons (mean difference 14.8(7.2), p=0.002) (Cunningham et al., 2002). There is potential that this variability contributes to different post-operative outcomes achieved as a result of over or under constraining the knee.

Recent reviews of graft tensioning have reported tensioning to range between 1N – 147.1N in animal, cadaveric and clinical studies (Arneja et al., 2009; Heis & Paulos, 2002). In human studies, a recent qualitative review of randomised controlled trials suggested 80N of tension in a semitendinosus gracilis graft produces less side-to-side difference (STSD) in anterior tibial displacement (Arneja et al., 2009). The paper goes on to note the limited homogeneity between tensioning protocols and also demonstrates the variability in the amount of tension utilized in human studies (Arneja et al., 2009).
While these reviews contribute to the body of knowledge on graft tension, none have specifically addressed the impact of graft tension on functional outcomes post ACLR. Additionally, there is limited quantitative analysis available to provide a comparison between outcome measures reported. Thus, the aim of this review was to investigate the effect of graft tension on patient specific functional outcomes post ACLR and undertake quantitative analysis of available data to determine if a particular tension produces superior functional outcomes post ACLR. It is our hypothesis that a medium tension range will produce a better functional outcome when compared to low and high-tension ranges.

3.3 Methods

Data Sources
A protocol outlining the search strategy, inclusion and exclusion criteria, quality assessment and data extraction was developed according to existing standards for systematic reviews (Liberati et al., 2009). To satisfy the aims of the review, the key search terms (full and truncated), used alone or in combination, were (1) anterior cruciate ligament or ACL, (2) tension, and (3) function. Publications in English language only, between 1950 and July 2012, were retrieved from the following databases: Cochrane Central Register of Controlled Trials, Physiotherapy Evidence Database (PeDro), Medical Literature Analysis and Retrieval System Online (Ovid Medline), Cumulative Index to Nursing and Allied Health Literature (CINAHL), Web of Knowledge, Scopus and Latin American and Caribbean Health Sciences Literature (LILACS).

Study Selection
Articles were excluded if the primary focus was not ACLR or the study used cadaver, animal or computer models on the basis that the objective of the review was patient-specific function. A single author (GK) reviewed initial search results and excluded papers where possible on the basis of title. Two authors (GK, MB) then reviewed the title and abstracts of the retrieved articles and excluded, based on the criteria set. The remaining titles and abstracts were de-identified for author, year, place of publication and country and were independently reviewed for inclusion, based on the criteria set (LC). These included: bone-patellar tendon-bone (BPTB) or semitendinosus gracilis graft (STG), included a tensioning method at fixation, reported a functional outcome measure, and the study design was National Health and Medical Research Council Australia (NHMRC) level of evidence III-1 or higher (NHMRC, 2009). A sample of articles reviewed for inclusion was assessed
by a second author to ensure reliability (GK). A third reviewer was available to arbitrate if consensus was not reached.

**Quality Assessment**

Articles were critically appraised (MB and PD) using a quality appraisal tool adapted from Bourke et al. (2010) and each article was given a score out of 12 based on the criteria presented in Table 3-1. All included articles were ranked according to the NHMRC levels of evidence scale (I-IV) (NHMRC, 2009).

### Table 3-1: Methodology Quality Assessment Score

<table>
<thead>
<tr>
<th>Methodology Criteria</th>
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<tbody>
<tr>
<td>1. Was there clear concealment of allocation?</td>
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<td>2. Were the inclusion and exclusion criteria clearly defined?</td>
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<tr>
<td>3. Were the treatment and control groups adequately described at entry and if so were the groups well matched or appropriate covariance adjustments made?</td>
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<tr>
<td>4. Were the surgeons experienced in the surgical procedures?</td>
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<tr>
<td>5. Were the rehabilitation programs other than trial options identical?</td>
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<tr>
<td>6. Were the outcome measures clearly defined in the text with a definition of ambiguous terms encountered?</td>
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<tr>
<td>7. Were the outcome assessors blind to assignment status?</td>
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<tr>
<td>8. Was a long-term follow-up performed (minimum 6 months)?</td>
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<tr>
<td>9. Was the timing of outcome assessment in both groups comparable and appropriate?</td>
</tr>
<tr>
<td>10. Was loss to follow-up reported and if so were less than 5% of patients lost to follow-up?</td>
</tr>
<tr>
<td>11. Was a sample size calculation performed?</td>
</tr>
<tr>
<td>12. The trial included an intention-to-treat analysis?</td>
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</table>

*Note: Each methodological criteria is scored as yes = 1 and no = 0 and a cumulative score calculated*

### Data Extraction

A data extraction tool was developed for the purpose of this review based on the Preferred Reporting Item for Systematic Reviews and Meta-Analysis (PRISMA) guidelines (Liberati et al., 2009) and all study characteristics were extracted by primary investigator (GK). The most frequently reported outcome measure was STSD in anterior tibial displacement measured with an arthrometer. Additional outcome measures included the International Knee Documentation Committee (IKDC) score, hamstrings and quadriceps strength, hop test and knee range of
movement. Other information extracted included measures of quality of life; follow up protocols and patient demographics (gender and age). All extracted data is presented in Table 3-2.
Table 3-2: Characteristics of included studies

<table>
<thead>
<tr>
<th>Randomised Studies</th>
<th>Patient Demographics</th>
<th>Study Characteristics</th>
<th>Arthrometer Measurement (mm)</th>
<th>Other Outcome Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Sample Size</td>
<td>M:F</td>
<td>Age</td>
<td>Graft Choice</td>
</tr>
<tr>
<td>(Kim et al., 2006)</td>
<td>43</td>
<td>29:19</td>
<td>27.1 – 22.6</td>
<td>STG</td>
</tr>
<tr>
<td>(Nicholas et al., 2004)</td>
<td>49</td>
<td>33:16</td>
<td>29:19</td>
<td>BPTB</td>
</tr>
<tr>
<td>(van Kampen et al., 1998)</td>
<td>38</td>
<td>27:11</td>
<td>30:7</td>
<td>BPTB</td>
</tr>
<tr>
<td>(Yasuda et al., 1997)</td>
<td>64</td>
<td>38:32</td>
<td>30:7</td>
<td>STG</td>
</tr>
<tr>
<td>(Yoshiya et al., 2002)</td>
<td>43</td>
<td>21:22</td>
<td>23:23</td>
<td>BPTB</td>
</tr>
</tbody>
</table>

Abbreviations: NR – Not Reported, Gr – Allocated study group, STG – Semitendinosus Gracilis graft, BPTB – Bone-Patella Tendon-Bone graft, IKDC – International Knee Documentation Committee score, Cat – IKDC Category, STSD – Side-to-side difference anterior tibial displacement, M:F – Male to Female participants

* Significance at the P = 0.05 level

** Significance at the P = 0.01 level
**Statistical Analysis**

STSD in anterior tibial displacement outcomes were expressed as effect sizes (ES) using Cohen’s $d$ method (Durlak, 2009). Two comparisons were performed including between-tension differences in mean values at a particular time divided by the pooled SD and between-time differences in mean values for a particular tension divided by the pooled SD. Results are presented as standardised mean difference (SMD) with 95% confidence interval (CI). Forrest plots and statistical analysis were completed using Excel® (v2008 for Mac, Microsoft Corporation, Redmond WA), Statistical Package for Social Sciences® (v 20.0, IBM, Chicago IL) and Review Manager® (v 5.1, Cochrane Collaboration, Copenhagen).

### 3.4 Results

724 articles were initially identified of which 267 were duplicates. Of the remaining 457, five were included in the review for assessment and analysis [Figure 3-1]. Pubmed returned the largest number of results ($n=292$), followed by Scopus ($n=214$) and Medline ($n=60$) with PeDro and LILACS returning no results. Eight review articles were identified in the search, the reference lists crosschecked prior to removal with one additional article being included. Cadaveric-based studies were the most common reason for exclusion ($n=256$) followed by articles not focused on ACLR ($n=105$) with the remaining being animal or computer based studies. Of the 50 articles assessed against inclusion criteria, eight articles progressed to quality assessment and five articles met the minimum requirement of NHMRC level III-1 or higher.
Quality of Included Studies

The methodological score for each study is presented in Table 3-3. The highest score achieved was 8/12. The mean (SD) score for the five included articles was 5.8 (1.3) with all articles failing to score in criteria 10 (loss to follow up reported), criteria 11 (sample size calculation performed) and criteria 12 (trial included an intention-to-treat analysis). All articles scored a point for criteria 3 (treatment and control groups well described, well matched) criteria 5 (rehabilitation programs other than trial options identical), criteria 6 (outcome measures clearly defined) and criteria 8 (minimum of 6 months follow-up performed).
Table 3-3: Methodology Assessment Outcomes

<table>
<thead>
<tr>
<th>Article</th>
<th>Criteria</th>
<th>Total Score</th>
<th>Evidence Level*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1 2 3 4 5 6 7 8 9 10 11 12</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Kim et al., 2006)</td>
<td>0 0 1 0 1 1 1 0 1 1 0 0</td>
<td>0 0 5</td>
<td>II</td>
</tr>
<tr>
<td>(Nicholas et al., 2004)</td>
<td>1 0 1 1 1 1 1 1 0 0 0 0</td>
<td>0 0 8</td>
<td>II</td>
</tr>
<tr>
<td>(van Kampen et al., 1998)</td>
<td>0 0 1 0 1 1 0 1 1 0 0 0</td>
<td>0 0 5</td>
<td>II</td>
</tr>
<tr>
<td>(Yasuda et al., 1997)</td>
<td>0 0 1 1 1 1 0 1 0 0 0 0</td>
<td>0 0 5</td>
<td>II</td>
</tr>
<tr>
<td>(Yoshiya et al., 2002)</td>
<td>0 1 1 0 1 1 0 1 1 0 0 0</td>
<td>0 0 6</td>
<td>II</td>
</tr>
</tbody>
</table>

* Based on NHMRC Level of Evidence Guidelines (NHMRC, 2009)

**Study Characteristics**

Participant numbers ranged from 38 to 64 participants with a bias towards males (approxiamtely 2:1). Participant ages were similar (24.7 +/- 3.6 years) as was follow up duration (19.5 +/- 5.0 months) across studies (Table 3-2).

**Initial Graft Tension**

Initial graft tension reported within the articles ranged from 20N – 147.1N. The most frequently reported tension was 20N (n=3) (Mae et al., 2010; van Kampen et al., 1998; Yasuda et al., 1997) with 40N reported in a further two studies (van Kampen et al., 1998; Yasuda et al., 1997). The remaining tensions reported included 45N, 78.5N, 90N, 117.7N and 147.1N.

**Side-to-side Difference in Anterior Tibial Displacement**

STSD in anterior tibial displacement as measured by an arthrometer was reported in all five articles (Kim et al., 2006; Nicholas et al., 2004; van Kampen et al., 1998; Yasuda et al., 1997; Yoshiya et al., 2002). Kim et al. (2006), Yoshiya et al. (2002) and van Kampen et al. (1998) reported no significant difference between groups immediately post surgery or greater than 12 months post surgery. Nicholas et al. (2004) reported significantly less STSD in anterior tibial displacement at 90N of tension when compared to 45N immeadiately post surgery (p=0.01). Yasuda et al. (1997) reported 80N of tension resulted in significantly less STSD in anterior tibial displacement when compared to 20N immediately post surgery (p=0.05) (Table 3-2).

Quantitative comparison of STSD in anterior tibial displacement between articles was performed using effect size represented as a SMD with 95% CI. Variability in reporting meant that data was
unavailable pre-operatively for two articles, post-operatively for three articles and ≥12 months for 1 article {Table 3-2}.

There was a reduction in the STSD in anterior tibial displacement from pre to post surgery for all articles (Kim et al., 2006; Nicholas et al., 2004; van Kampen et al., 1998; Yasuda et al., 1997; Yoshiya, Andrish, Manley, & Bauer, 1987). 80N of initial tension produced the largest effect (SMD -2.98; 95% CI -3.82, -2.14) (Yasuda et al., 1997) while 45N produced the smallest effect (SMD -1.19; 95% CI -1.83, -0.54) (Nicholas et al., 2004) [Figure 3-2]. Between pre and ≥12 months post surgery the greatest effect was produced at 78.5N (SMD -2.45; 95% CI -3.40, -1.51) (Kim et al., 2006) and again the smallest effect produced at 45N of initial tension (SMD -0.98; 95% CI -1.61, -0.35) (Nicholas et al., 2004) [Figure 3-3]

Between-tension comparison at ≤2 weeks post surgery demonstrated the largest effect in favor of 80N compared to 20N (SMD 0.76; 95% CI 0.17-1.35) (Yasuda et al., 1997) and the smallest effect towards 40N compared to 20N (SMD 0.37; 95% CI -0.21-0.95) [Figure 3-5] (Yasuda et al., 1997). At ≥12 months post surgery, the largest effect was towards 78.5N compared to 147.1N (SMD -0.58; 95% CI -1.29-0.13) (Kim et al., 2006) and the smallest effect towards 40N compared to 20N (SMD 0.06; 95% CI -0.58-0.70) (van Kampen et al., 1998) [Figure 3-4].
STSD in anterior tibial displacement was reduced in all presented studies from pre to post surgery regardless of tension. 80N of tension produced the largest effect and 45N resulted in the smallest effect.
STSD in anterior tibial displacement was reduced in all studies at ≥12 months when compared to pre-surgery. 78.5N produced the largest effect and 45N produced the smallest effect

**Figure 3-4: Effect size calculations between tensions at 12 months post surgery**

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Low Tension</th>
<th>High Tension</th>
<th>Std. Mean Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean  SD</td>
<td>Total</td>
<td>Mean  SD</td>
</tr>
<tr>
<td>Kim et al 78.5N v 147.1N</td>
<td>1.3 1.4</td>
<td>16</td>
<td>2.4 2.2</td>
</tr>
<tr>
<td>Kim et al 78.5N vs 117.7N</td>
<td>1.3 1.4</td>
<td>16</td>
<td>2.1 1.9</td>
</tr>
<tr>
<td>Kim et al 117.7N v 147.1N</td>
<td>2.1 1.9</td>
<td>16</td>
<td>2.4 2.2</td>
</tr>
<tr>
<td>vanKampen et al 20N v 40N</td>
<td>2.6 1.4</td>
<td>19</td>
<td>2.5 1.8</td>
</tr>
<tr>
<td>Nicholas et al 45N v 90N</td>
<td>3 2.2</td>
<td>22</td>
<td>2.2 1.6</td>
</tr>
</tbody>
</table>

In each article reviewed there was a consistent trend towards an effect in favour of a medium tension. The largest effect was towards 78.5N when compared to 147.1N and the smallest effect produced was between 20N and 40N

**Figure 3-5: Effect Size Calculations Between Tensions at 2 Weeks Post Surgery**

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Low Tension</th>
<th>High Tension</th>
<th>Std. Mean Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean  SD</td>
<td>Total</td>
<td>Mean  SD</td>
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<tr>
<td></td>
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<tr>
<td></td>
<td>2.2 2.4</td>
<td>23</td>
<td>1.4 1.8</td>
</tr>
<tr>
<td></td>
<td>1.4 1.8</td>
<td>23</td>
<td>0.6 1.7</td>
</tr>
<tr>
<td></td>
<td>2.4 2.4</td>
<td>22</td>
<td>1.1 1.7</td>
</tr>
<tr>
<td></td>
<td>2.2 2.4</td>
<td>23</td>
<td>0.6 1.7</td>
</tr>
</tbody>
</table>

At ≤2 weeks post surgery the effect in all cases was in favour of the higher tension, which in this data set is in the medium tension range. The largest effect was towards 80N when compared to 20N and the smallest effect towards 40N when compared to 20N
Additional Outcome Measures

The IKDC Subjective Knee Form was collected in two articles (van Kampen et al., 1998; Yoshiya et al., 2002). However, van Kampen et al. (1998) was the only paper to report a comparison and showed no significant difference between 20N and 40N of tension.

Two articles compared knee range of movement between various tensions with both reporting no significant difference in either loss of flexion or extension between groups at 20-24 months post surgery (Nicholas et al., 2004; Yasuda et al., 1997). Two articles compared quadriceps and hamstring strength as a percentage of injured and non injured with both articles reporting no significant difference between tensions (Kim et al., 2006; Yasuda et al., 1997).

3.5 Discussion

Graft choice, tunnel placement, initial graft tension and angle of fixation are all thought to contribute to functional outcomes in ACLR (Bylski-Austrow et al., 1990; Friederich & O'Brien, 1998; Nabors et al., 1995). This review aimed to evaluate the influence of initial graft tension on such outcomes. Quantitative comparison suggests a trend towards medium tension (78.5N-90N) producing less STSD in anterior tibial displacement as measured by an arthrometer for STG or BPTB autografts. This, however, does not provide sufficient evidence when referring directly to patient function. Research has shown little correlation between STSD in anterior tibial displacement and patient function (Cull, O'Connor, Sharp, & Tang, 2005; Irrgang, 2008; Livingston & Wislar, 2012; Schuld & Totten, 1994; Wiebe, Kaczorowski, & MacKay, 2012), and the current literature failed to adequately report more appropriate measures.

STSD in anterior tibial displacement was the primary outcome measure in all five articles and the only outcome reported in sufficient detail to enable effect size calculation to be performed. Despite consistency in reporting, there was inadequate homogeneity between methodologies to enable pooling of data for meta-analysis. The articles reviewed used a wide range of initial graft tensions and selected various methodologies for measuring anterior tibial displacement.

Regardless of methodology, effect size calculations demonstrated a consistent trend towards medium tensioning producing less STSD in anterior tibial displacement. Comparison between pre-surgery and ≤2 weeks or ≥12 months identified an effect in favour of 80N and 78.5N, respectively. Furthermore, 80N and 78.5N produced the largest effect when compared to 20N and 147.1N,
respectively. In combination, these findings suggest that a medium tension may produce a superior outcome in STSD in anterior tibial displacement. This is consistent with the findings of Nicholas et al. (2004) and Yasuda et al. (1997) who reported a significant reduction in STSD in anterior tibial displacement at 80N and 90N, respectively. In contrast, van Kampen et al. (1998) reported no significant difference between 20N and 40N and concluded 20N was sufficient when selecting a BPTB graft. However, in our analysis of treatment effect, the difference between 20N and 40N was the smallest of all the data analysed (SMD 0.06; 95% CI -0.58-0.70) and, therefore, it would be reasonable to conclude that had a medium tension been included a similar finding may have been reached.

While the review offers clinically relevant recommendations regarding ACLR outcomes, the relationship between STSD in anterior tibial translation and patient function has not been established (Irrgang, 2008; Livingston & Wislar, 2012; Wiebe et al., 2012). Although evidence supports the measuring of STSD in anterior tibial displacement as a valid method for detecting ACL deficiency, there is no correlation between measured laxity and functional outcomes (Cull et al., 2005; Feller, Webster, & Gavin, 2001; Irrgang, 2008; Livingston & Wislar, 2012; Schuldt & Totten, 1994; Wiebe et al., 2012). A recent study by Kocher, Steadman, Briggs, Sterett, and Hawkins (2004) demonstrated no correlation between STSD laxity and activities such as walking, jumping, running, stairs and return to sport, concluding that laxity is not a good indicator of functional success. This is supportive of an earlier study by Eastlack et al. (1999) who reported patients with laxity post ACLR differed significantly in their functional outcomes and concluded that patients are better characterised as either copers or noncopers based on their functional capability not the measured laxity. Based on the literature available, it is difficult to draw a definitive conclusion as to which tension produces a superior functional outcome.

Limitations
A number of studies did address the effect of initial graft tension on post-surgical functional outcomes, however, the methodological quality was often poor and the reporting of results was inconsistent {Table 3-2}. Based on the assessment of quality {Table 3-3}, only one article demonstrated robust methodology sufficient to draw a valid conclusion (Nicholas et al., 2004). The remaining articles scored 5 – 6 out of 12 and caution should be applied when interpreting these results. Arneja et al. (2009) conducted a qualitative review on graft tensioning and reported limitations in a similar set of articles showing significant limitations in post hoc power analysis, questioning the validity of the results published. Further studies with high methodological quality specifically investigating patient-specific functional outcomes are required to draw more definitive
conclusions around function. Additionally, consistency in study design will allow meta-analysis to be conducted in the future to draw definitive conclusions as to the effect of initial graft tension on function.

**Conclusions**

The objective of this review was to systematically assess the literature to determine if a particular initial graft tension results in superior outcomes post ACLR. From the review, there is a trend towards an initial graft tension of 78.5N-90N resulting in a reduced STSD in anterior laxity as measured by an instrumented knee laxity device. However, there is insufficient evidence to conclude if patient-specific function is improved at any specific tension.
A randomised controlled trial to investigate the effect of graft
tensioning method on functional outcomes post ACLR: Intentions
and complications

Based on the findings from the systematic review in the previous chapter, 79N – 90N of tension appeared more effective at restoring STSD in anterior tibial translation when compared to tensions below 79N or above 90N. However, the effect of different tensions and tensioning methods on patient outcome was unable to be determined. Therefore, the aim of the second study was to investigate the effect of graft tensioning method on patient functional outcomes following ACLR. The primary objective of the study was to determine if method of graft tensioning (the use of a tensioning device to deliver a consistent force of 80N versus manual tension) affected functional outcome up to 12 months following ACLR surgery.

Clinically, tension is often not quantified during ACLR and the manual method of tensioning is practiced widely with successful outcomes reported (Lewis et al., 2008). However, laboratory based studies investigating the manual method have suggested a lack of inter-tester and intra-tester reliability among surgeons (Cunningham et al., 2002; O'Neill et al., 2011). Findings from these studies suggest that variability increases the risk of over or under constraining the knee, which may result in pain, laxity and or loss of function (Arnold, Verdonschot, & van Kampen, 2005; Fleming et al., 2013; Friederich & O'Brien, 1998). Techniques such as ‘one-handed maximal pull’ have been used in an attempt to standardise manual tension between surgeons. However, this technique has been shown to be unsuccessful at improving the reliability of this method in cadaver-based trials (Cunningham et al., 2002; O'Neill et al., 2011).

In response, the use of a tensioning device has been suggested to achieve a consistent approach to graft tension, hence, minimizing the risk of over or under-constraining the knee (Cunningham et al., 2002; O'Neill et al., 2011). Therefore, it can be hypothesised that a tensioning device will result in improved patient outcomes post ACLR compared to the manual method.

Therefore, a randomised controlled trial comparing tensioning method on functional outcomes post ACLR was conducted. Drawing on the conclusions from chapter 3, the effectiveness of applying 80N of tension with a tensioning device was compared to the commonly reported manual tension
using a maximum one handed pull with respect to patient function at 12 months post ACLR. However, while conducting this study, several pragmatic complications were encountered that impacted on the study design. Thus, this chapter is to outlines the study design, presents the complications encountered and provides a rationale for the reporting of the RCT findings presented in chapter 5.

**Study design**

A double blinded prospective randomised clinical trial was designed with participants randomised into two parallel groups according to the un-blinded application of either MT using a maximum one handed pull or a graft tensioned with a tensioning device at 80N of tension. The postoperative collection of outcome measures were performed by a physiotherapist blinded to the method of tensioning and there were no additional factors identified that required additional stratification. The study was designed according to Consolidated Standards of Reporting Trial (CONSORT) 2001 framework (Moher, Schulz, & Altman, 2001).

To address the research question, the International Knee Documentation Committee Score (IKDC) (Irrgang et al., 2001) was selected as the primary outcome measure to assess patient function. Secondary outcome measures included the Modified Lysholm Score (Tegner & Lysholm, 1985), the Tegner Score (Tegner & Lysholm, 1985) the Single Leg Hop Test for Distance (SLHD) (Daniel et al., 1988) and STSD in anterior tibial displacement using a knee arthrometer (KT-1000 MEDmetric® Corporation, San Diego, California) to measure laxity. At the time of study design and planning (January – April 2006), a minimally clinically important difference (MCID) for the IKDC was not available in the literature and other existing studies contained insufficient data to accurately determine sample size. Therefore, a decision was made to begin data collection until a sufficient sample was available upon which to perform a sample size calculation. Preliminary data from the RCT was analysed at 3 months post surgery (MT n=5; TD n=5). Based on the study population, the MT group reported a mean (SD) IKDC of 69.7(10.01) compared to 63.2(3.65) in the TD group. Using this data, an effect size of 0.86 was calculated. Calculations with a power of 0.8 and an alpha of 0.05 using a two tailed methodology (Machin & Fayers, 2010) computed a sample size of 23 participants per group. Allowing a 10% drop out rate, the aim was to recruit 25 participants per group, which we considered achievable within the study time frames.
Complications in conducting the study

Prior to commencing the study, retrospective data relating to ACLR surgical rates for the QEII Jubilee Hospital Orthopaedic Department was collected to determine study feasibility. In the two years preceding the study, approximately 52 ACLR were performed per year between the two participating surgeons suggesting the study was feasible. However, during the first year of the study two events occurred that were beyond the control of the research team, which severely impacted on participant recruitment.

The first event was a change in funding structure within the Department of Orthopaedics at the QEII Jubilee Hospital. Driven by public health indicators to address surgical wait times in key areas, the QEII Jubilee Hospital implemented priorities to be given to joint arthroplasty, resulting in an increase in ACLR wait times and a rapid reduction in procedures between the two participating surgeons. Then, one of the participating surgeons resigned from the QEII Jubilee Hospital Orthopaedics Department. Therefore, within 12 months of the commencement of the study, the recruitment pool declined from approximately 52 per year to an average of approximately six per year. This unforeseen set of circumstances first led to an inability to reach the intended sample size requirement. Second, the loss of one surgeon resulted in an unequal distribution of patients between surgeons (surgeon one n=15; surgeon two n=8). While the distribution was uneven, the use of an independent randomisation table of block size four for each surgeon ensured that each surgeon had equal number of TD and MT participants.

In an attempt to ameliorate this situation, strategies to increase participant recruitment were employed to maximise the statistical power of the study (Spilker, 1991). Initially, additional surgeons at the QEII Jubilee Hospital with comparable experience in performing ACLR (n=3) were approached to participate in the study. However, due to a lack of experience using a tensioning device and/or an unwillingness to change current practice, no additional surgeons could be recruited. The expansion of the trial to include an additional trial site was also explored. However, the additional trial site that was identified required research assistant support and staff training beyond the financial capacity of an unfunded PhD study. Therefore, the most pragmatic solution identified was to lengthen the study recruitment duration, which was extended from September 2008 to May 2010. Unfortunately, over the course of this extended time period, a total of 23 participants were all that were recruited to the study.

In addition to the complications experienced during recruitment, five participants (22%) were lost to follow up at 12 months despite using numerous strategies such as follow up phone calls, sending
correspondence via mail and contacting next of kin. The characteristics of the population lost were examined to offer an explanation for this loss to follow up. This population tended to be younger (26.5 +/- 5.4) and the primary reason was a change in contact details (n=4). Furthermore, all participants were recruited through the public health service and it could be argued that this population may experience various social factors contributing to the loss of follow up over time.

Reporting the study findings

Despite the limitations of the study, the research findings still provide relevant information to guide further research relating to graft tensioning during ACLR. It is widely accepted that an RCT is a ‘gold standard’ for minimising bias in research (Bederman, Chundamala, & Wright, 2010; Boutron, Ravaud, & Nizard, 2007; Shore, Nasreddine, & Kocher, 2012) and the study presented in chapter 5 meets many of the factors considered critical for quality. However, the small sample size and failure to reach statistical power limits the generalisability of the results. Failing to achieve an adequate sample size is a recognised risk in orthopaedic research and factors such as high loss to follow up rates; restrictive eligibility criteria and patient reluctance to participate are important to consider (Shore et al., 2012; Simunovic, Devereaux, & Bhandari, 2008). Despite the lower numbers recruited into the study, the recruitment rate in this study was high (82%). Therefore, while the results cannot be generalised to the wider community, there is some confidence that the sample was representative of the QEII ACLR population.

The following chapter (Chapter 5) presents the results of the RCT despite the small sample size which was achieved. In the context of a PhD thesis, the reporting of the study demonstrates that the candidate understands research methodology and can report the study appropriately. The conclusions drawn in the chapter are based on the available data. In order to maintain the style and format of the thesis the study is presented as a journal manuscript. The limitations of the study are discussed and clearly outlined with supporting information provided by this bridging chapter to provide context.
Does graft tensioning method during anterior cruciate ligament reconstruction affect patient functional outcome 12 months post ACL reconstruction: A randomised controlled trial

Based on the findings from chapter three, 79N – 90N is optimal in restoring anterior stability when compared to tensions <79N or >90N, however, the effect on patient outcome is unclear. However, many surgeons use a manual method of tensioning, which has been shown to be unreliable. Therefore, this chapter contributes to the thesis by detailing a randomised controlled trial comparing tensioning method on outcome post ACLR. Drawing on the conclusions of the systematic review, we compared the effectiveness of tensioning at 80N with a tensioning device to manually tensioning the graft on functional outcomes at 12 months post surgery.

The chapter is adapted with minor additions and alterations to formatting to maintain consistency of the thesis from the following publication:

5.1 Abstract

**Purpose**
The aim of this study was to investigate if the method of graft tensioning (manual tensioning versus use of a tensioning device) during anterior cruciate ligament reconstruction (ACLR) affected functional outcomes up to 12 months following surgery.

**Material and Methods**
Twenty-three participants undergoing primary ACLR were randomised into two groups based on tensioning method. The tensioning device group (n=10) underwent an anatomical single bundle reconstruction using a semitendinosus gracilis autograft tensioned at 80N using a Linvatec® (Largo, Florida, USA) SE™ graft tensioner applied at 30 degrees. The manually tensioned group (n=13) underwent the same surgical protocol; however, tensioning was performed manually with a one-handed maximum pull applied at 30 degrees. Participants were assessed pre-operatively and then at 2 weeks, 3 months, 6 months and 12 months post surgery.

**Results**
There were no significant differences between the two groups for functional outcomes including the International Knee Documentation Committee score (p=0.76), Lysholm score (p=0.12), Tegner score (p=0.96) and Single Leg Hop Test for Distance (p=0.89). There was also no significant difference in side-to-side difference (STSD) in anterior tibial displacement, as measured by the KT-1000, between the groups (p=0.63). The relative risk for greater than 5mm of STSD in anterior tibial displacement was 0.8(95% CI 0.45 – 1.44).

**Conclusion**
Tensioning method did not affect the functional outcomes of participants at 12 months post ACLR. The higher incidence of STSD in anterior tibial displacement in the manually tensioned group may indicate that a tensioning device reduces the risk of excessive STSD in anterior tibial displacement. However, further research with a larger sample size is required.

**Clinical relevance**
Both manual tensioning and tensioning with a device result in a satisfactory functional outcome post ACLR and either method as selected by the surgeon would be acceptable.
5.2 Introduction

The incidence of anterior cruciate ligament injury is increasing with Janssen et al. (2012) reporting a 14% increase from 2003 to 2008 with higher activity rates in the general population considered a major contributor (Csintalan, Inacio, & Funahashi, 2008; Gianotti et al., 2009; Moses, Orchard, & Orchard, 2012; Prodromos, Han, Rogowski, Joyce, & Shi, 2007). With surgical management widely accepted as the primary treatment option, there has also been a concomitant increase in the number of anterior cruciate ligament reconstructions (ACLR) performed annually (Gianotti et al., 2009; Janssen et al., 2012; Moses et al., 2012). As the primary treatment option, there is an expectation from patients that surgical intervention will enable them to return to pre-injury levels of function. Thus, a focus on improving surgical technique is essential to achieving optimal patient outcomes (Irrgang, 2008; Paxton, Kymes, & Brophy, 2010; Zywiel, Mahomed, Gandhi, Perruccio, & Mahomed, 2013).

A recent meta-analysis reported that less than half (between 33 and 41%) of those undergoing ACLR achieve a ‘normal’ outcome, as defined by The International Knee Documentation Committee Score (Biau et al., 2007). Pain, extension loss and inability to return to pre-injury levels of function are the most commonly reported limitations (Biau et al., 2007; Chalmers et al., 2013; Martins et al., 2008). The continual refinement of surgical methods to optimize the restoration of normal knee biomechanics is considered essential to minimizing such limitations (Gadikota et al., 2010; Seon et al., 2007). One such surgical variable is initial graft tension (Arneja et al., 2009; Kim et al., 2006; Kirwan, Bourke, Chipchase, Dalton, & Russell, 2013; Woo et al., 2006). There are predominantly two methods of tensioning used in ACLR. The first requires the surgeon to apply the tension manually while the alternative involves the use of a tensioning device (O'Neill et al., 2011; Sherman et al., 2012).

In the manual method, the surgeon is required to determine the amount of tension based on clinical judgment and expertise without any external reference. Although a widely used method, the literature reports a lack of inter-tester and intra-tester reliability among surgeons when using such a method (Cunningham et al., 2002; O'Neill et al., 2011). Greater variability increases the risk of either insufficient tension resulting in increased knee laxity, instability, pain and loss of function or excessive tension producing increased joint forces, loss of range and poor functional outcome (Arnold et al., 2005; Fleming et al., 2013; Friederich & O'Brien, 1998). Attempts to use standardized terms such as “one-handed maximal pull” have failed to improve the reliability of this method (Cunningham et al., 2002; O'Neill et al., 2011).
Alternatively, surgeons have adopted the use of tensioning devices to achieve a reliable and consistent approach to graft tension to minimize over or under-constraining the knee (Cunningham et al., 2002; O'Neill et al., 2011). Although these devices improve the reliability of the tension applied, there is still debate over what the optimal tension is for achieving the best outcome. A recent systematic review suggests that the optimal tension is between 78.5N – 90N to reduce side-to-side difference (STSD) in anterior tibial displacement post operatively (Kirwan et al., 2013). However, the review noted a lack of consistency in surgical methodology, variability in the amount of tension applied, poor reporting of functional outcomes and a paucity of research; thus, limiting the ability to draw conclusions about the ideal tension to maximize patient function (Kirwan et al., 2013).

To date there has been no published studies that we can identify that have directly compared the effect of tensioning method on functional outcomes post ACLR. With a lack of clarity as to the optimal method to achieve the best outcome for patients, we undertook a prospective randomised controlled trial to compare the effect of tensioning method on functional outcome post ACLR. The aim of our study was to determine if the utilization of a tensioning device with a set tension resulted in better functional outcomes post ACLR when compared to the manual technique.

5.3 Methodology

A double blind prospective randomised controlled trial was undertaken on patients presenting to the Orthopaedic Department of Queen Elizabeth II Jubilee Hospital, Brisbane, Australia for surgical reconstruction of an anterior cruciate ligament injury. Ethical approval for the study was granted through the University of Queensland Medical Research Ethics Committee and the Princess Alexandra Human Research Ethics Committee (Appendix B). All surgical procedures were undertaken between September 2006 and May 2010. Patients undergoing a primary ACLR using a semitendinosus gracilis (STG) autograft were recruited if they were 18 years or older and able to provide informed consent (Appendix C and Appendix D). Participants undergoing ACLR with any graft other than STG, revision ACLR, history of previous lower limb injury affecting knee function or a co-morbidity preventing participation in the rehabilitation protocol, were excluded from the study.
Participants were randomised into one of two groups using a block randomisation table of size four. The Tensioning Device (TD) group underwent graft tensioning prior to tibial fixation using a Linvatec Corporation© (Largo, Florida, USA) SE™ Graft tensioning system at a combined tension of 80N applied at 30 degrees knee flexion. This tension was selected based on the findings of a systematic review (Kirwan et al., 2013). The manual tensioned (MT) group underwent graft tensioning prior to tibial fixation with the surgeon applying tension by hand at 30 degrees knee flexion as per standard practice. A sealed envelope containing the tensioning method to be utilized was placed in the medical chart and opened at the time of surgery. All procedures were completed by one of two experienced orthopaedic surgeons. Each surgeon was familiar and experienced in the use of both the Linvatec SE Graft Tensioner as well as the manual tensioning method. Prior to the study, the surgeons agreed on a standardized surgical protocol and observed the procedure performed by the other surgeon to ensure standardization. Thus, the surgical technique and fixation was as standardized as possible between surgeons and group. Participants were assessed pre-operatively and two weeks, three, six and 12 months post-operatively. Throughout the follow up period, both the participant and the assessors were blinded to the tensioning method utilized.

Surgical Protocol

All participants underwent an arthroscopic single bundle anatomic ACLR using an STG autograft. The surgical procedure was standardized except for the tensioning method. The patient was positioned supine and draped in the standard fashion, and two arthroscopic portals were established. A closed tendon stripper was inserted through a transverse anteromedial incision at the pes-anserinus and the semitendinosus and gracilis grafts harvested. The graft was prepared and the diameter measured. The tibial and femoral tunnels were placed anatomically in the footprint of the anterior cruciate ligament stump. The graft was passed through the tibial tunnel and into the femoral tunnel. The graft was fixed on the femoral side with an Endobutton. Prior to tibial fixation, tension was applied using one of the two methods: For the TD group a Linvatec© (Largo, Florida, USA) SE™ Graft Tensioner was fixed to the tibia and the graft sutures attached to the tensioner. A differential tension of 60N and 40N were initially applied to the semitendinosus and gracilis grafts, respectively while in 30 degrees of knee flexion. The knee was cycled 15 times through a full range of motion and tension was adjusted accordingly again at 30 degrees of knee flexion until stable at 50N and 30N for semitendinosus and gracilis, respectively to achieve a total tension of 80N. The graft was then secured at the tibia with a Bioscrew. In the MT group, the surgeon held the sutures attached to the distal end of the harvested graft and applied a manual maximum pull equally distributed across all 4 strands of the graft while the knee was cycled 15 times through a full range
of motion; after which the graft was fixed at the tibia using a Bioscrew while the knee was in 30 degrees of knee flexion.

Rehabilitation Protocol

All participants followed a standardized accelerated rehabilitation protocol consisting of six phases (Appendix E). Phases progressed from pre-operation to return to sport or normal activity. All rehabilitation was undertaken under the guidance of a trained physical therapist that progressed the patients through the protocol in a consistent manner. Phase one focused on pre-operative preparation through maintenance of knee range of motion (ROM) and strength. The post-operative phase (phase two) encouraged early weight bearing with crutches as required in the first week, progressing to full weight bearing without crutches by the end of week one. Early ROM exercises were encouraged with a limit between normal hyperextension and 110 degrees of flexion in the first 2 weeks. In addition, standardized advice was provided on the management of pain and swelling including the use of rest, ice, compression and elevation. Phase three (2 – 6 weeks) progressed ROM to normal physiological range while introducing proprioceptive and strength training. Phase four (6 – 12 weeks) progressed strength and proprioception and aimed for patient confidence in knee stability. Phase five (3 – 6 months) aimed for 85% of limb strength compared to the uninjured leg and a return to non-contact activities. The final stage (Phase six) focused on activity specific training to facilitate return to normal activity between nine and twelve months post surgery.

Clinical Assessment

The International Knee Documentation Committee Score (IKDC) subjective evaluation form (Irrgang et al., 2001) was selected as the primary outcome measure to assess function. Secondary outcome measures included the Modified Lysholm Score (Tegner & Lysholm, 1985), the Tegner Score (Tegner & Lysholm, 1985) and the Single Leg Hop Test for Distance (SLHD) (Daniel et al., 1988). In addition, to quantify knee laxity, STSD in anterior tibial displacement at 30 pounds and maximal manual displacement were measured using a knee arthrometer (KT-1000 MEDmetric® Corporation, San Diego, California). All measures were assessed pre surgery and repeated post-operatively at two-weeks, three months, six months and 12 months. The SLHD was not performed at two weeks and three months post-operative due to the risk posed to graft integrity. One of three blind assessors who underwent training and familiarization in the application and delivery of each outcome measure performed the assessment of each participant. For the purposes of this study graft failure was defined as a complete tear to the reconstructed ACL graft with the participant requiring a revised reconstruction.
Sample size calculation
Preliminary data from the RCT was analysed at 3 months post surgery (MT n=5; TD n=5). Based on the study population, the MT group reported a mean (SD) IKDC of 69.7(10.01) compared to 63.2(3.65) in the TD group. Using this data, an effect size of 0.86 was calculated. Calculations with a power of 0.8 and an alpha of 0.05 using a two tailed methodology (Machin & Fayers, 2010) computed a sample size of 23 participants per group. Allowing a 10% drop out rate, the aim was to recruit 25 participants per group.

Statistical Analysis
An intention-to-treat analysis was conducted with available data from all randomised participants. Statistical analysis was completed using SPSS 20.0 software package (SPSS Inc., Chicago, IL, USA). A linear mixed model was used to evaluate the effect of tension method on outcomes post ACLR. Tension group (i.e. TD or MT) and time (pre, 2 weeks, 3 months, 6 months and 12 months) were entered as factors with participant age and days from injury to surgery as covariates. A fixed effect model was selected, based on the assumption that heterogeneity within the group was constant as they were sampled from a specific population (Peng & Lu, 2012) and the significance level was set at $p = 0.05$. Prior to running the linear mixed model, outliers were investigated and removed based on the criteria of greater than three standard deviations from the mean (Armitage, Matthews, & Berry, 2002). A single data point was removed from ‘time from injury to surgery’ in the pre-operative analysis as the timeframe was greater than three standard deviations from the mean. Data was evaluated for normality and confirmed through statistical analysis using a Shapiro-Wilk test. For baseline comparison of continuous outcome measures, an analysis of variance (ANOVA) was used to determine statistical differences between the two groups. The effect of tension on the Tegner was conducted using a Mann-Whitney U test as an ordered ranked variable. All other dichotomous variables were analyzed using a Chi Squared test and a risk ratio calculation was used to compare the incidence below and above 5mm of STSD in anterior tibial displacement at 12 months post surgery.

5.4 Results
Twenty-eight participants were eligible to participate in the study. Five participants did not progress to randomisation in the study due to declining (n=3) or not meeting the study inclusion criteria (n=2). The remaining 23 participants were allocated and included for post-surgical follow up.
Figure 5-1 details the participant flow through the study. Of the 23 participants included in post-surgical follow up, one participant from the TD group and two from the MT group were lost to follow up at 12 months post surgery and two participants from the TD group experienced graft failure secondary to a traumatic event [Figure 5-1].

There was no significant difference between the TD and MT groups with respect to age, gender and time from injury to surgery {Table 5-1}. In addition, there was no difference in baseline outcome measures between the two groups except for the Lysholm score ($p = 0.02$) where the TD group had a significantly lower score {Table 5-1}. 
Figure 5-1: Participant flow diagram
### Table 5-1: Baseline demographics of participants

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Manually Tensioned Group (n=13)</th>
<th>Tensioning Device Group (n=10)</th>
<th>Significance</th>
<th>F Score (DoF)</th>
<th>Statistical Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender, Male : Female</td>
<td>8 : 5</td>
<td>6 : 4</td>
<td>P = 0.94</td>
<td>_</td>
<td>Chi Squared</td>
</tr>
<tr>
<td>Age (years), mean (SD)</td>
<td>30.3 (9.45)</td>
<td>29.8 (6.7)</td>
<td>P = 0.89</td>
<td>0.02(1, 22)</td>
<td>ANOVA</td>
</tr>
<tr>
<td>Time from injury to surgery (days), mean (SD)</td>
<td>578.0 (180.4)</td>
<td>348.7 (303.8)**</td>
<td>P = 0.07</td>
<td>3.9(1, 18)</td>
<td>ANOVA</td>
</tr>
<tr>
<td>Concomitant meniscal injury, Yes : No</td>
<td>7 : 6</td>
<td>2 : 8</td>
<td>P = 0.10</td>
<td>_</td>
<td>Chi Squared</td>
</tr>
</tbody>
</table>

**Baseline outcome measures**

| IKDC Score, mean (SD)                                | 51.3 (15.7)                      | 44.7 (14.7)                  | P = 0.32     | 1.0(1, 21)   | ANOVA           |
| Lysholm Score, mean (SD)                             | 62.0 (18.76)                     | 45.2 (10.4)                  | P = 0.02*    | 6.3(1, 21)   | ANOVA           |
| Tegner Score, mean (SD)                              | 3.3 (1.5)                        | 2.4 (1.6)                    | P = 0.23     |               | Mann-Whitney U Test |
| KT-1000 STSD (mm), mean (SD)                         |                                 |                               |              |              |                 |
| 30 pounds                                            | 5.18 (2.9)                       | 4.46 (2.9)                   | P = 0.57     | 0.3(1, 21)   | ANOVA           |
| Maximum manual displacement                          | 6.38 (2.8)                       | 4.63 (4.5)                   | P = 0.28     | 1.2(1, 21)   | ANOVA           |
| SLHD STSD (cm), mean (SD)                            | 35.1 (26.1)                      | 32.95 (44.5)                 | P = 0.89     | 0.02(1, 21)  | ANOVA           |

SD – Standard deviation, IKDC – International Knee Documentation Committee, SLHD – Single Leg Hop Test for Distance, STSD – Side-to-side difference, DoF – Degrees of freedom
*Significant at P < 0.05 level; **Data removed as >3 standard deviations from mean
Table 5-2: Mean (SD) of collected outcome measures

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Pre TD (n=10)</th>
<th>Pre MT (n=13)</th>
<th>Post TD (n=10)</th>
<th>Post MT (n=13)</th>
<th>3 months TD (n=10)</th>
<th>3 months MT (n=13)</th>
<th>6 months TD (n=10)</th>
<th>6 months MT (n=13)</th>
<th>12 Months TD (n=10)</th>
<th>12 Months MT (n=13)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>KT-1000</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>STSD ATD at 30 pounds (mm)</td>
<td>4.5 (2.9)</td>
<td>5.2 (2.9)</td>
<td>-0.1 (3.1)</td>
<td>0.8 (2.2)</td>
<td>3.1 (1.4)</td>
<td>3.8 (3.3)</td>
<td>3.4 (1.7)</td>
<td>3.5 (2.3)</td>
<td>3.9 (2.2)</td>
<td>2.7 (3.3)</td>
<td>0.63</td>
</tr>
<tr>
<td>KT-1000</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>STSD ATD Max manual displacement (mm)</td>
<td>4.6 (4.5)</td>
<td>6.4 (2.8)</td>
<td>0.3 (3.6)</td>
<td>1.2 (2.5)</td>
<td>2.8 (1.5)</td>
<td>3.7 (2.7)</td>
<td>3.0 (2.1)</td>
<td>3.5 (2.5)</td>
<td>3.5 (4.0)</td>
<td>2.4 (4.0)</td>
<td>0.69</td>
</tr>
<tr>
<td>IKDC (Score)</td>
<td>44.7 (14.7)</td>
<td>51.4 (15.8)</td>
<td>34.4 (9.3)</td>
<td>37.1 (14.0)</td>
<td>64.5 (7.4)</td>
<td>67.1 (11.8)</td>
<td>69.7 (13.0)</td>
<td>75.8 (10.7)</td>
<td>84.7 (7.6)</td>
<td>82.4 (11.9)</td>
<td>0.76</td>
</tr>
<tr>
<td>Lysholm Score</td>
<td>45.2 (10.5)</td>
<td>62.0 (18.7)</td>
<td>51.1 (18.3)</td>
<td>62.4 (15.3)</td>
<td>76.8 (14.1)</td>
<td>81.1 (10.5)</td>
<td>78.1 (15.6)</td>
<td>89.0 (6.3)</td>
<td>91.4 (6.6)</td>
<td>88.2 (11.7)</td>
<td>0.12</td>
</tr>
<tr>
<td>Tegner Score</td>
<td>2.4 (1.6)</td>
<td>3.3 (1.5)</td>
<td>1.9 (1.4)</td>
<td>1.6 (1.3)</td>
<td>3.7 (1.9)</td>
<td>4.0 (1.5)</td>
<td>4.7 (2.4)</td>
<td>6.0 (2.0)</td>
<td>5.4 (1.4)</td>
<td>6.8 (2.2)</td>
<td>0.29</td>
</tr>
<tr>
<td>OLHD STSD (cm)</td>
<td>33.0 (44.5)</td>
<td>35.1 (26.1)</td>
<td></td>
<td>25.1 (16.9)</td>
<td>31.8 (19.8)</td>
<td>10.9 (12.9)</td>
<td>10.9 (12.9)</td>
<td>20.6 (18.9)</td>
<td>0.89</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Significant at P > 0.05

STSD – Side-to-side difference, ATD – Anterior tibial displacement, IKDC – International Knee Documentation Committee, OLHD – One Leg Hop Test for Distance

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Patient reported outcome measures

As anticipated, both the TD and MT groups improved significantly from baseline to 12 months with respect to the IKDC ($p < 0.01$), Tegner ($p = <0.01$) and Lysholm ($p = <0.01$) scores. There were no significant group-by-time interactions for any of the patient reported outcomes {Table 5-2}. Post hoc analysis identified the MT group scored significantly higher in the Lysholm score at 6 months post surgery, indicating a better functional outcome at that point in time ($p = 0.046$) (Appendix F).

Objective outcome measures

The TD and MT groups improved significantly over time with respect to STSD in anterior tibial displacement as measured by the KT-1000 at 30 pounds, and maximum manual displacement ($p < 0.01$; $p = 0.02$, respectively). Side-to-side differences in the SLHD also improved significantly over time ($p = 0.04$). There was no significant group-by-time interaction between the groups for STSD in anterior tibial translation at 30 pound ($p = 0.63$), maximum manual displacement ($p = 0.69$) or STSD on SLHD ($p = 0.9$) (Appendix F).

At 12 months post-surgery the relative risk for more than 5mm of STSD in anterior tibial displacement was 0.8(95% CI 0.45 – 1.44); (MT group n = 2, TD group n = 1) in favour of the TD group when compared to the MT group. However, no statistical difference between the two groups was observed based on a Chi Squared analysis ($p = 0.41$). Two participants in the TD group reported a graft failure requiring revision prior to 12-month follow up as a result of trauma.

5.5 Discussion

Initial graft tension in ACLR is considered an important factor for optimizing outcomes post surgery (Arneja et al., 2009; Kim et al., 2006; Kirwan et al., 2013; Nicholas et al., 2004; van Kampen et al., 1998; Yasuda et al., 1997; Yoshiya et al., 2002). The aim of this study was to determine if tensioning method affected the functional outcome post ACLR. Overall, no significant differences between the two groups were found; with both tensioning methods producing similar functional outcomes up to 12 months post ACLR.

The outcomes achieved in the MT and TD groups were consistent with previous studies relating to patient reported function post ACLR (Biau et al., 2007; Hussein, van Eck, Cretnik, Dinevski, & Fu,
Both groups had significant improvements in function from baseline to 12 months post ACLR, evidenced by the IKDC (p<0.01), Lysholm (p<0.01) and Tegner scores (p<0.01); however, there was no significant difference between the two groups. At 6 months, it was noted that the MT group achieved a significantly better outcome based on the Lysholm score when compared to the TD group (p = 0.046). However, based on the lack of correlation between the findings on the Lysholm and that reported in the Tegner and IKDC, it is difficult to draw any definitive conclusions. The Lysholm score was also significantly better at pre-surgery in the MT group (p=0.02) and it is plausible that the findings at both these time points are a result of the small sample size and a greater risk of type II error. All other functional outcomes showed no significant interaction between group and time, indicating that both MT and TD methods are effective for restoring function up to 12 months post ACLR.

The assessment of AP stability post ACLR using the KT-1000 to determine STSD in anterior tibial displacement was also evaluated. Analysis demonstrated a significant reduction in STSD in anterior tibial displacement from pre to 12 months post surgery (p<0.01) in both groups; however, no significant difference between the groups was detected. Manual maximum displacement at 12 months showed a mean (SD) of 3.5 (4.0) and 2.4 (4.0) in STSD in anterior tibial displacement for the TD and MT groups, respectively. These results are comparable to previous studies, which report a mean STSD difference from 0.6mm to 2.5mm using a STG graft with a similar surgical protocol and post-operative follow up (Kim et al., 2006; Kondo et al., 2008; Yasuda et al., 1997). Although the mean STSD reported in our study (3.5mm TD group; 2.4mm MT group) is greater than that reported by similar studies (0.6mm – 2.5mm), it is still within a clinically acceptable range. The literature on STSD in anterior tibial displacement categorizes less than 5mm of STSD as a successful outcome with respect to stability, which is consistent with the findings in this study and other similar research (Arneja & Leith, 2009; Daniel et al., 1985; Tyler et al., 1999). Therefore, it can be concluded that, regardless of tensioning method, patients undergoing ACLR with a STG graft successfully restore knee stability at 12 months post surgery.

Due to the nature of how the tension was produced in the MT group, we were unable to quantify the amount of tension applied during surgery. We are, therefore, unable to conclude if the amount of tension applied manually was different to that achieved in the TD group. It is possible that, by chance, the MT group received a tension similar to that achieved in the TD group, resulting in similar outcomes. Alternatively, based on the fact that both surgeons performed the manual
techniques as well as the tensioning device, there may have been a ‘learned effect’ influencing the amount of tension produced during manual tensioning. If both groups received a similar amount of tension, then this could account for the lack of difference between the groups.

The sample size in this study was small and did not meet the sample size calculation for the primary outcome measure (n=23 per group). Furthermore, in considering the secondary outcome measures, post hoc analysis suggests that a sample size of 297 participants per group would be required to ensure a statistical power of 0.80 (alpha = 0.05) is met for STSD in anterior tibial translation. This would require a large multi-centre trial that was outside of the scope of this study. Based on the observed trend with regards to the incidence of AP laxity, such a study may provide valuable insight into the effect of tensioning method on consistency in ACLR.

Additional limitations of this data include the failure of randomisation to distribute the groups equally based on the Lysolm score where the TD group had a significantly lower score compared to the MT group at baseline. This could indicate that the TD group may have been at a lower functional level based on this measure. Furthermore, the study only conducted follow-up for 12 months and is unable to hypothesise the impact of graft tensioning method on long-term outcomes. Finally, by not quantifying the amount of manual tension applied, we are unable to comment on the difference in tension that was actually applied between the two groups.

In summary, this study suggests that the method of tensioning has no effect on the functional outcomes 12 months post ACLR. Despite the ability to deliver consistency between subjects in the amount of tension applied when using a tensioning device, it appears that a manual method applied by an experienced surgeon produces the same outcome. Based on the findings of this study, further research with an adequately powered sample size is necessary to determine if a tensioning device reduces the incidence of AP laxity greater than 5mm.
6 Development of a valid and reliable survey investigating graft tensioning practices among Australian orthopaedic surgeons

The systematic review (study one) identified that application of medium tension (79N-90N) to the ACL graft during reconstruction reduces STSD in anterior tibial translation compared to low (<79N) or high (>90N) tension. However, the optimal tension for restoring patient function remains unclear. Furthermore, a prospective randomised controlled trial (study two) found no difference in STSD in anterior tibial translation or functional outcomes when tensioning with a device at 80N was compared to manual tensioning. In the absence of definitive evidence to guide best practice, a survey of orthopaedic surgeons was undertaken to identify factors influencing clinical practice regarding tensioning. In this chapter, the design, development and reliability testing of a survey evaluating these factors is presented.

The chapter outlines the methodology taken to design, validate and test the reliability of a survey on tensioning practices in ACLR. Initially, the framework used to develop the survey is presented. Survey development is then presented in a manner that reflects the framework including planning, designing, piloting, reliability testing, distributing and analyzing the instrument.
6.1 Introduction

6.1.1 Conducting a survey

Surveys are a systematic approach to the collection and statistical analysis of information that define the knowledge, attitudes, beliefs or behaviours of a defined population (Aday & Cornelius, 2006; Groves, 2004; Jackson, Collier, Box-Steffensmeier, & Brady, 2008). Health based surveys are a cost effective method for policymakers, health professionals and consumers to evaluate health outcomes and influence current health practice (Aday & Cornelius, 2006). With the potential to guide health practice and influence patient outcomes, the accuracy and integrity of the survey findings are paramount (Aday & Cornelius, 2006). To develop a survey that delivers accurate findings, sources of survey error must be minimised and clear research aims maintained (Grimmer & Bialocerkowski, 2005).

The process by which survey data is collected and represented can be summarised in three stages. Initially, information is collected from an individual based on a specific set of characteristics that define a population. Secondly, individual data is grouped together and statistically analysed to summarise the sample representative of a population. Finally, the information is interpreted and extrapolated to represent the identified population (Groves, 2004). The aggregation and summation of individual responses to represent a population is sensitive to numerous sources of error, which can bias findings and affect the ability to draw accurate conclusions (Czaja & Blair, 2005; Groves, 2004; Jackson & Furnham, 2000). An understanding of such sources of error and the methods to minimise their impact are, therefore, essential to conducting an effective survey.

Error associated with conducting a survey

There are four common sources of survey error, corresponding with the different stages of data collection and analysis. The first source of error relates to how information is collected from an individual. Referred to as ‘measurement error’, the survey, interviewer, or the respondent can create bias leading to inaccurate or imprecise data, compromising the validity of the information collected (Aday & Cornelius, 2006; Dillman, 2000; Groves, 2004). Common factors such as the language of the survey, construction of the questions and the method of delivery influence a respondent’s answer (Dillman, 2000; Groves, 2004). As a result, inconsistent data that is not representative of the sample may be collected, compromising the validity of the findings. Minimising measurement error
is reliant on effective planning, the development of a valid and reliable instrument and ensuring that the design of each question addresses the aims of the survey.

The second source of error is ‘sampling error’ and results from only a proportion of the identified population being surveyed (Groves, 2004). As more of a population is sampled, the risk of bias is reduced and the accuracy of the information is improved. For example, if 100% of the identified population were included, then sampling error would not exist. However, as the sample size decreases the ability of the data to accurately represent the entire population is diminished. Therefore, methods that maximise response rate are critical to minimising sampling error.

The third source of error is ‘coverage error’, which occurs when members of the population are not given equal chance to participate. Poor sampling strategies are the primary cause of coverage error, resulting in the exclusion of respondents based on certain characteristics. Importantly, if the characteristics of the excluded sample are relevant to the survey aims, proposed conclusions will be inaccurate and therefore not a true representation of the population (Groves, 2004). An example of coverage error would be conducting a survey on national health outcomes and only including the private health sector. In this instance, the outcomes of people who use a public health service would be excluded; thus, findings would not be representative of all health outcomes nationally and, therefore, could be misleading. Minimising coverage error requires effective sampling strategies to ensure all members of the population have equal chance of responding to the survey.

The final source of error is ‘nonresponse error’, which arises when the sample characteristics of respondents are different to the characteristics of non-respondents in a way that is relevant to the study (Groves, 2004). For example, a survey conducted in English investigating multicultural issues within health care may receive a significant nonresponse from non-English speaking participants; thus, biasing the survey results and affecting the accuracy of any findings. Minimising nonresponse error is multifactorial and requires careful survey design and sampling methods to ensure that members of the population with certain characteristics are not more likely to fail to respond.

6.1.2 Designing a framework for conducting health surveys

In considering the sources of survey error, a quality framework was developed to minimise the impact of bias and ensure data accuracy. Based on available literature, five key stages were identified to guide the framework including: (1) planning the research, (2) designing the survey, (3) piloting the survey, (4) distributing the survey and (5) analysing and presenting the data (Aday &
Cornelius, 2006; Czaja & Blair, 2005; Dillman, 1978, 2000; Fink, 2006; Groves, 2004; Jackson et al., 2008; Sue & Ritter, 2007). Each stage was further expanded to identify processes relevant to the research. Figure 6-1 outlines the final framework that was constructed.

6.2 Survey development

The following section is presented with reference to the framework outlined in Figure 6-1.

6.2.1 Planning the survey

The purpose of the survey was primarily to identify the factors that influence clinical practice among orthopaedic surgeons with regards to graft tensioning. The research population was defined as orthopaedic surgeons currently registered in Australia who conduct ACLR surgery on an annual basis. Based on the objectives of the research and the defined population, three clear aims were outlined: (1) to identify current graft tensioning practices among Australian orthopaedic surgeons, (2) to identify the factors that influence graft-tensioning protocols and (3) to determine surgeon reported patient outcomes.
Figure 6-1: Methodological framework for conducting the survey
**Literature review to identify a relevant valid and reliable survey tool**

A review of the literature was conducted to identify surveys investigating graft tensioning in ACLR. Eleven studies were identified that conducted a survey primarily related to ACLR surgical practice, however, of the 11 studies identified, only one included a specific question on graft tension (McRae, Chahal, Leiter, Marx, & MacDonald, 2011). This study investigated the method of tensioning; however, did not explore other factors such as the amount of tension or the rationale for graft tensioning (McRae et al., 2011). No previously validated or reliable instrument was available in the current literature; hence, the development of a new survey was required.

**Ethical approval**

Approval to conduct the study was granted by the University of Queensland Human Ethics Committee (Appendix G).

6.2.2 Designing the survey

The instrument was developed using an iterative process consisting of three phases [Figure 6-2].

**Figure 6-2: Processes involved in survey development**
Survey type
An observational cross sectional survey was deemed most appropriate to address the aims of the study. Observational surveys are descriptive studies, effective at defining characteristics at a point in time while allowing aggregation of data to represent a population. Furthermore, observational studies are considered relatively cost effective and easy to administer (Fink, 2006; Jackson et al., 2008).

Survey mode
A web-based survey was selected as the primary mode. Web-based surveys are easily administered, effective at reaching specialised populations and are inexpensive (Groves, 2004). Furthermore, a sample of Australian orthopaedic surgeons (n=8), sourced by the authors, indicated that a web-based method was the preferred method for conducting a survey. Although a series of papers reviewed by VanGeest, Johnson, and Welch (2007) and Kellerman and Herold (2001) suggest that mail surveys have higher response rates, publication date of the included studies was such that they may not be representative of current trends. Furthermore, a recent study by Cunningham et al. (2015) demonstrated equivocal response rates among medical specialists using web-based methods, supporting the decision to select this method.

Expert input to establish themes
In the initial phase, expert input was sought by conducting a structured interview with six orthopaedic surgeons regarding current practice and to gain their opinion related to graft tensioning. The aim of the interview was to establish themes and key issues to guide the content of the initial draft survey. Each surgeon was asked a set of open-ended questions developed by the researcher and the supervisory team {Table 6-1}. The information collected was discussed and acted as a platform to develop the first draft of the survey.
### Table 6-1: Structured surgeon interviews

<table>
<thead>
<tr>
<th>Open questions</th>
<th>Summarised responses</th>
</tr>
</thead>
</table>
| 1. How do you tension a graft during ACLR? | • Manual hand tension with sustained maximal pull (estimates 50-70N)  
• Manual hand tension (approx. 50N) in ext or near ext (10 deg)  
• Mitek manual tensioning device 15 pounds  
• Linvatec graft tensioner 80N 90 deg  
• Linvatec graft tensioner 80N  
• Sub maximal 1 handed pull until knee feels stable through range |
| 2. Why do you prefer that method of tensioning? | • Using TD Makes the tensioning process objective and reproducible  
• 20 years of excellent clinical outcomes subjectively and objectively  
• Able to get a better outcome with greater tension achieved with the device  
• Able to reproduce desired tension to get better outcomes  
• Most common and no evidence for device  
• Device is not necessarily accurate so manual is better  
• Device can increase surgical time as it is fiddly |
| 3. Do you think your tension is important for patient outcomes? | • Very important  
• Important  
• Equally important as other methods  
• Getting exact tension not so important  
• Important to get stable knee through tension  
• Tension is important for taking up viscoelastic creep and not dependent on specific amount of tension |
| 4. What other factors influence your tensioning method? | • It depends on the materials used e.g BPTB or STG  
• I consider the age of the patient when determining tension  
• No correlation with other factors in my experience  
• Tension is the same for each person and there is no evidence to support variation |

**Deg – degrees, TD – tensioning device, BPTB – bone-patella tendon-bone, STG – semitendinosus gracilis**

**Designing the survey questions**

Based on the homogenous characteristics of the defined population, questions were designed in a manner that provided concise and direct questioning, using language that was professional and specific to the target population. Questions were grouped in a logical order according to the themes outlined in Table 6-1 (Dillman, 2000; VanGeest et al., 2007). The first draft (Appendix H) consisted of 25 questions, primarily grouped by tensioning method and further sub-divided into sections based on approach to tensioning, factors influencing graft tensioning and functional outcomes. Questions predominantly included closed questions, yes/no (n=5), select one response (n=9), select
multiple responses (n=2) or provide a rating (n=4). The remaining five questions required an open response from the respondent.

The survey was designed with a focus on making it easy to complete, short in length, while gathering accurate information relative to the survey aims (Dillman, 2000; Dillman, Sinclair, & Clark, 1993; Kellerman & Herold, 2001; VanGeest et al., 2007). Furthermore, the design included question skip logic, which directs respondents only to relevant questions based on previous responses. Skip logic ensures only relevant questions are answered and reduces completion time, both of which having been shown to improve response rate (Dillman, 2000; VanGeest et al., 2007). Questions were ordered such that opening questions were simple, interesting and directly related to the topic and subsequent questions flowed according to cognitive link and level of importance. Questions relating to demographic information were incorporated at the end of the survey (Dillman, 2000).

6.2.3 Piloting the survey

Assessing validity
An expert panel was convened to ensure face and content validity. The panel consisted of the six surgeons involved in the initial interviews. Each member was an experienced orthopaedic surgeon, who performed regular ACLR. Each participant reviewed the first draft of the survey and provided written feedback on the design. Information collected was discussed with the research team and integrated into the survey to develop a second iteration for pilot testing. The log of changes between the first and second draft are outlined in Table 6-2. Changes made to the survey included modifications to the options provided for a question (n=3), correction of professional terminology (n=6), removal of questions deemed irrelevant (n=3), and sub-division of a question into multiple questions to improve clarity (n=1).
Table 6-2: Log of changes from first to second iteration of survey

<table>
<thead>
<tr>
<th>Item</th>
<th>1st draft</th>
<th>Suggested change</th>
<th>2nd draft</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preamble to survey</td>
<td>All questions relate to your PREFERRED approach to anterior cruciate ligament reconstruction (ACLR). We acknowledge that factors change based on a number of clinical presentations but we are interested in your preferred approach assuming ideal conditions.</td>
<td>Change <strong>PREFERRED</strong> to <strong>STANDARD</strong> to improve clarity</td>
<td>General Information regarding survey</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Include information differentiating pre-tensioning from tension prior to fixation to improve clarity</td>
<td>All questions relate to your <strong>STANDARD</strong> approach to anterior cruciate ligament reconstruction (ACLR). We acknowledge that factors change based on a number of clinical presentations but we are interested in your standard approach assuming ideal conditions</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Graft tension for the purpose of this survey refers specifically to the process where tension is applied to the graft prior to tibial fixation. It DOES NOT relate to the process where tension is applied during pre-conditioning and preparation of the graft</td>
</tr>
<tr>
<td>Q1</td>
<td><strong>Part 1</strong> Restoring anterior-posterior knee laxity</td>
<td>Change <strong>laxity</strong> to <strong>stability</strong> as language better reflects the goal of tensioning</td>
<td>Restoring anterior-posterior knee stability</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q4</td>
<td><strong>Option 3 – Amount of tension varies based on the patient</strong></td>
<td>Remove this option as it replicates question 5 which asks if tension is standardised</td>
<td>Option 3 removed</td>
</tr>
<tr>
<td>Item</td>
<td>1&lt;sup&gt;st&lt;/sup&gt; draft question</td>
<td>Suggested change</td>
<td>2&lt;sup&gt;nd&lt;/sup&gt; draft question</td>
</tr>
<tr>
<td>------</td>
<td>-------------------------------</td>
<td>------------------</td>
<td>-------------------------------</td>
</tr>
<tr>
<td>Q7</td>
<td>Open response - Please estimate the amount of tension you apply?</td>
<td>As manual tension is not quantified it would be better to offer a range of tensions for participants to estimate</td>
<td>Select 1 – How much tension would you estimate is produced manually to the whole graft?</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• &lt;20N (&lt;5lbs)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• 20N-40N (5-8lbs)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• 41N-60N (9-13lbs)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• 61N-80N (14-17lbs)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• 81N-100N (18-22lbs)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• &gt;100N (&gt;22lbs)</td>
</tr>
<tr>
<td>Q10</td>
<td>Option 1 – Full extension</td>
<td>Change to hyperextension as this better reflects the position of end of range</td>
<td>Option 1 – Full hyperextension</td>
</tr>
<tr>
<td>12</td>
<td>Cost of the tensioning device</td>
<td>Difficult to answer as depending on work environment may not purchase equipment so just refer to the method as a whole</td>
<td>Cost of method</td>
</tr>
<tr>
<td>Part 7</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>The accuracy of the tensioning device</td>
<td>Confusing as this is being answered by those undertaking manual tension. Replace with sensory feedback as this may better reflect an aspect that influences someone using the manual method</td>
<td>Sensory feedback from the manual pull</td>
</tr>
<tr>
<td>Part 8</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 6 – 2: Log of changes from first to second iteration of survey (continued)

<table>
<thead>
<tr>
<th>Item</th>
<th>1st draft question</th>
<th>Suggested change</th>
<th>2nd draft question</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q17</td>
<td>Please state the range of tensions you apply (Only answer the options which applies to your standard approach):</td>
<td>Question is unclear and needs to be reviewed. May need an example</td>
<td>Please state the minimum and maximum amount of tension you would apply e.g 20N-80N would imply 20N is the minimum and 80N is the maximum applied to a strand based on the factors identified in the previous question (Only answer the option that applies to your standard approach)</td>
</tr>
<tr>
<td>Q18</td>
<td>Option 1 – Full extension</td>
<td>As per Q10</td>
<td>Option 1 – Full hyperextension</td>
</tr>
<tr>
<td>Q20</td>
<td>Cost of the tensioning device</td>
<td>As per 12 part 7</td>
<td>Cost of method</td>
</tr>
<tr>
<td>Q25</td>
<td>Patello-femoral pain</td>
<td>Previous option asks about anterior knee pain which includes patella-femoral pain and are difficult to differentiate</td>
<td>Remove Q25 Part 2</td>
</tr>
</tbody>
</table>
Test retest reliability

The second draft of the survey (Appendix I) underwent pilot testing to determine test retest reliability. A sample population of registered orthopaedic surgeons currently performing ACLR were recruited for the pilot. Eight Australian orthopaedic surgeons who were not involved in the development phase of the survey consented to participate in the study (Appendix J and Appendix K). Demographic data for the pilot group is presented in Table 6-3. All members were male, had performed an ACLR in the last 12 months, and had a range of experience and expertise, representative of the profession.

Table 6-3: Demographic data for expert panel

<table>
<thead>
<tr>
<th>Geographical setting</th>
<th>Frequency (n=8)</th>
<th>Percent</th>
<th>Cumulative percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metro</td>
<td>8</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Regional</td>
<td>0</td>
<td>0%</td>
<td>100%</td>
</tr>
<tr>
<td>Rural</td>
<td>0</td>
<td>0%</td>
<td>100%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Years Experience</th>
<th>Frequency</th>
<th>Percent</th>
<th>Cumulative percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;5</td>
<td>2</td>
<td>25%</td>
<td>25%</td>
</tr>
<tr>
<td>5-9</td>
<td>1</td>
<td>12.5%</td>
<td>37.5%</td>
</tr>
<tr>
<td>10-14</td>
<td>2</td>
<td>25%</td>
<td>62.5%</td>
</tr>
<tr>
<td>15-19</td>
<td>0</td>
<td>0%</td>
<td>62.5%</td>
</tr>
<tr>
<td>&gt;20</td>
<td>3</td>
<td>37.5%</td>
<td>100%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Average ACL per year</th>
<th>Frequency</th>
<th>Percent</th>
<th>Cumulative percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;10</td>
<td>2</td>
<td>25%</td>
<td>25%</td>
</tr>
<tr>
<td>10-20</td>
<td>1</td>
<td>12.5%</td>
<td>37.5%</td>
</tr>
<tr>
<td>21-30</td>
<td>1</td>
<td>12.5%</td>
<td>50%</td>
</tr>
<tr>
<td>31-40</td>
<td>2</td>
<td>25%</td>
<td>75%</td>
</tr>
<tr>
<td>41-50</td>
<td>1</td>
<td>12.5%</td>
<td>87.5%</td>
</tr>
<tr>
<td>&gt;50</td>
<td>1</td>
<td>12.5%</td>
<td>100%</td>
</tr>
</tbody>
</table>

Participants were provided a paper copy of the survey to complete. At one-week post completion, each participant was re-sent the same survey via email to assess test retest reliability. Based on the observational cross sectional design of the survey, a measure of percentage agreement was deemed most appropriate to determine survey stability over time (Litwin, 1995). A survey codebook was created to detail survey structure, content and layout to assist with data entry and analysis (Sue & Ritter, 2007). Individual responses from each participant were categorised according to coded items and initial and final responses were matched for each participant. Data was entered into Microsoft
Excel® v2011 for Mac (Microsoft Corporation, Redmond WA) and intra-rater reliability was assessed at the individual item level. Open-ended questions were removed for the purpose of test retest reliability. An a priori percentage agreement of ≥75% was considered acceptable based on previous published reliability studies (Saelens et al., 2006; Singh et al., 2011). A total of 30 coded items were included in the analysis to determine test retest reliability. Of the 30 items, 90% demonstrated ≥75% agreement (n=27) with three items achieving below the 75% (Table 6-4). Of the three items identified, two demonstrated moderate reliability (60% - 74%) and one demonstrated poor reliability (<60%) (Singh et al., 2011). The three items were discussed with the research team and modifications to the questions was agreed upon to improve the clarity of the questions before inclusion in the final survey.

In addition to assessing the reliability of the survey, the pilot group completed an evaluation of the survey (Appendix L) and provided a rating on the key themes of ease of: completion, clarity of questions, appropriateness of language, survey flow and length. Participants were asked to rate each attribute on a four-point scale with 1 indicating poor and 4 indicating excellent; the results are summarised in Figure 6-3. The opportunity to provide specific feedback on individual questions and their relevance to the survey was also offered. Based on the reliability testing and evaluation results, final changes were made to the survey and summarised in Table 6-5. Appendix M outlines the final version of the national survey.

Additional feedback from the pilot group was sought on the preferred distribution method and survey length. Based on group discussion, a web-based survey, distributed by email with a maximum length of 10 minutes, was agreed as most appropriate for the survey population.
Figure 6-3: Results from survey evaluation

Ease:
- Excellent: 100%
- Good: 90%
- Fair: 80%
- Poor: 70%

Clarity:
- Excellent: 0%
- Good: 10%
- Fair: 20%
- Poor: 30%

Language:
- Excellent: 30%
- Good: 60%
- Fair: 70%
- Poor: 80%

Flow:
- Excellent: 40%
- Good: 50%
- Fair: 60%
- Poor: 70%

Length:
- Excellent: 50%
- Good: 60%
- Fair: 70%
- Poor: 80%
Table 6-4: Percentage agreement for test retest reliability

<table>
<thead>
<tr>
<th>No</th>
<th>Item content</th>
<th>Description</th>
<th>Agreement between tests (n=8)</th>
<th>Percentage agreement (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>*Importance of tension in stability</td>
<td>Rating scale (1 – 3)</td>
<td>5</td>
<td>62.5</td>
</tr>
<tr>
<td>2</td>
<td>Importance of tension in function</td>
<td>Rating scale (1 – 3)</td>
<td>6</td>
<td>75</td>
</tr>
<tr>
<td>3</td>
<td>Preferred choice of graft</td>
<td>Select 1 of 6</td>
<td>8</td>
<td>100</td>
</tr>
<tr>
<td>4</td>
<td>Preferred method of tensioning</td>
<td>Select 1 of 2</td>
<td>8</td>
<td>100</td>
</tr>
<tr>
<td>5</td>
<td>Description of manual method</td>
<td>Yes/No</td>
<td>6</td>
<td>100</td>
</tr>
<tr>
<td>6</td>
<td>Do you standardise tension</td>
<td>Select 1 of 6</td>
<td>7</td>
<td>87.5</td>
</tr>
<tr>
<td>7</td>
<td>Are you able to estimate tension</td>
<td>Yes/No</td>
<td>7</td>
<td>87.5</td>
</tr>
<tr>
<td>8</td>
<td>At what angle of flexion do you tension</td>
<td>Select 1 of 6</td>
<td>7</td>
<td>87.5</td>
</tr>
<tr>
<td>9</td>
<td>Have you trialled the alternative method</td>
<td>Yes/No</td>
<td>8</td>
<td>100</td>
</tr>
<tr>
<td>10</td>
<td>Influence of outcome on choice of method</td>
<td>Rating scale (1 – 3)</td>
<td>7</td>
<td>87.5</td>
</tr>
<tr>
<td>11</td>
<td>Influence of evidence on choice of method</td>
<td>Rating scale (1 – 3)</td>
<td>7</td>
<td>87.5</td>
</tr>
<tr>
<td>12</td>
<td>Influence of assistant on choice of method</td>
<td>Rating scale (1 – 3)</td>
<td>6</td>
<td>75</td>
</tr>
<tr>
<td>13</td>
<td>Influence of operation time on choice of method</td>
<td>Rating scale (1 – 3)</td>
<td>7</td>
<td>87.5</td>
</tr>
<tr>
<td>14</td>
<td>*Influence of attachment to tibia on choice of method</td>
<td>Rating scale (1 – 3)</td>
<td>3</td>
<td>37.5</td>
</tr>
<tr>
<td>15</td>
<td>Influence of training on choice of method</td>
<td>Rating scale (1 – 3)</td>
<td>7</td>
<td>87.5</td>
</tr>
<tr>
<td>16</td>
<td>Influence of cost on choice of method</td>
<td>Rating scale (1 – 3)</td>
<td>7</td>
<td>87.5</td>
</tr>
<tr>
<td>17</td>
<td>Influence of sensory/accuracy on choice of method</td>
<td>Rating scale (1 – 3)</td>
<td>7</td>
<td>87.5</td>
</tr>
<tr>
<td>18</td>
<td>Geographical area of practice</td>
<td>Select 1 of 3</td>
<td>8</td>
<td>100</td>
</tr>
<tr>
<td>19</td>
<td>Years of experience</td>
<td>Select 1 of 5</td>
<td>7</td>
<td>87.5</td>
</tr>
<tr>
<td>20</td>
<td>Number of ACLR per annum</td>
<td>Select 1 of 6</td>
<td>7</td>
<td>87.5</td>
</tr>
<tr>
<td>21</td>
<td>Average follow up post surgery</td>
<td>Select 1 of 5</td>
<td>8</td>
<td>100</td>
</tr>
<tr>
<td>22</td>
<td>Incidence of anterior knee pain</td>
<td>Rating scale (1 – 4)</td>
<td>8</td>
<td>100</td>
</tr>
<tr>
<td>23</td>
<td>Incidence of general knee pain</td>
<td>Rating scale (1 – 4)</td>
<td>8</td>
<td>100</td>
</tr>
<tr>
<td>24</td>
<td>Incidence of lack of end range flexion</td>
<td>Rating scale (1 – 4)</td>
<td>7</td>
<td>87.5</td>
</tr>
<tr>
<td>25</td>
<td>Incidence of lack of end range extension</td>
<td>Rating scale (1 – 4)</td>
<td>7</td>
<td>87.5</td>
</tr>
<tr>
<td>26</td>
<td>*Incidence of quadriceps weakness</td>
<td>Rating scale (1 – 4)</td>
<td>5</td>
<td>62.5</td>
</tr>
<tr>
<td>27</td>
<td>Incidence of hamstring weakness</td>
<td>Rating scale (1 – 4)</td>
<td>6</td>
<td>75</td>
</tr>
<tr>
<td>28</td>
<td>Incidence of joint instability</td>
<td>Rating scale (1 – 4)</td>
<td>8</td>
<td>100</td>
</tr>
<tr>
<td>29</td>
<td>Inability to return to previous level of function</td>
<td>Rating scale (1 – 4)</td>
<td>7</td>
<td>87.5</td>
</tr>
<tr>
<td>30</td>
<td>Incidence of graft failure</td>
<td>Rating scale (1 – 4)</td>
<td>8</td>
<td>100</td>
</tr>
</tbody>
</table>

*Item did not meet 75% agreement criteria*
<table>
<thead>
<tr>
<th>Item</th>
<th>2nd draft question</th>
<th>Suggested change</th>
<th>Final draft question</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preamble to survey</td>
<td>General Information regarding survey</td>
<td>Include comment on consent</td>
<td>General Information regarding survey</td>
</tr>
<tr>
<td></td>
<td>All questions relate to your STANDARD approach to anterior cruciate ligament reconstruction (ACLR). We acknowledge that factors change based on a number of clinical presentations but we are interested in your standard approach assuming ideal conditions</td>
<td></td>
<td>All questions relate to your STANDARD approach to anterior cruciate ligament reconstruction (ACLR). We acknowledge that factors change based on a number of clinical presentations but we are interested in your standard approach assuming ideal conditions</td>
</tr>
<tr>
<td></td>
<td>Graft tension for the purpose of this survey refers specifically to the process where tension is applied to the graft prior to tibial fixation. It DOES NOT relate to the process where tension is applied during pre-conditioning and preparation of the graft</td>
<td></td>
<td>Graft tension for the purpose of this survey refers specifically to the process where tension is applied to the graft prior to tibial fixation. It DOES NOT relate to the process where tension is applied during pre-conditioning and preparation of the graft</td>
</tr>
<tr>
<td>Q10</td>
<td>Option 2 – Near full extension</td>
<td>As part of pilot some selected other and recorded 5 or 15 degrees, which would be considered near full extension. Therefore give reference to guide what near full extension means</td>
<td>Option 2 – Near full extension (0-15 degrees)</td>
</tr>
<tr>
<td>Item</td>
<td>2nd draft question</td>
<td>Suggested change</td>
<td>Final draft question</td>
</tr>
<tr>
<td>------</td>
<td>-----------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Q17</td>
<td>Please state the minimum and maximum amount of tension you would apply e.g. 20N-80N would imply 20N is the minimum and 80N is the maximum applied to a strand based on the factors identified in the previous question (Only answer the option that applies to your standard approach)</td>
<td>Question not clear, split into two questions to be clear about minimum and maximum tension</td>
<td>Q17 - Please state the minimum amount of tension you would apply based on the factors identified in the previous question (Only answer the option(s) that applies to your standard approach and indicate force in newtons or pounds)</td>
</tr>
</tbody>
</table>

Q18 - Please state the maximum amount of tension you would apply based on the factors identified in the previous question (Only answer the option(s) that applies to your standard approach and indicate force in newtons or pounds)

| Option 2 – Near full extension | As per Q10 | Now Q19 due to above change Option 2 – Near full extension (0-15 degrees) |

| Surgeon Name                  | Included prior to Q21 | This should be included at the end and an optional question. If only for the purpose of prize allocation and follow up then no need to be compulsory | Relocated to end of survey as optional question as included as per below:

Surgeon Name:
This information is only being collected to identify eligible participants to win the Mont Blanc pen being offered in appreciation for your time. Name will be collected independently and not linked to the responses submitted. Providing this information is optional |
6.2.4 Survey distribution

Identifying the sampling frame

The proposed survey population was defined as orthopaedic surgeons currently practicing in Australia. Under the Health Practitioner National Law Act 2009, all practising orthopaedic surgeons must be registered with the Australian Health Practitioner Regulation Authority (AHPRA). Based on Australian medical workforce data, an estimated 1,302 orthopaedic surgeons were registered with AHPRA (RACS, 2011) at the time of survey distribution. However, the orthopaedic profession in Australia is further divided into sub-specialties reflective of the primary clinical caseload undertaken by the surgeon. The Australian Orthopaedic Association (AOA) identifies 11 areas of sub-specialty, one of which relates to the knee. As a recognised sub-specialty, orthopaedic surgeons identifying with a sub-specialty in knee were deemed likely to perform ACLR on an annual basis and, thus, represented the target population. Therefore, in accordance with the survey aims, a non-random purposive approach to sampling on a population defined as Australian orthopaedic surgeons who identify with the sub specialty of knee was decided (Jackson & Furnham, 2000).

Three methods were used to identify the target population. The first utilised the ‘Find A Surgeon’ function provided on the AOA website (www.aoa.org.au), a service that allows the public to search for a member based on sub-specialty. The second collected member details published on the Australian Knee Society website (www.aks.org.au). Finally, a general Internet search was conducted with the parameters: (1) orthopaedic surgeon, (2) knee, and (3) anterior cruciate ligament to identify additional possible participants.

Methods to maximise response rate

An adequate response rate minimises survey bias and ensures an accurate representation of the target population (VanGeest et al., 2007). Response rate among medical practitioners has been shown to be 14% less than other populations, indicating the importance of adopting specific strategies to maximise response (Kellerman & Herold, 2001). A review investigating nonresponse among medical practitioners reported time as the primary reason, followed by a perceived lack of benefit, concerns over confidentiality, question bias, inadequate options to respond and survey length (VanGeest et al., 2007). Factors with proven effectiveness in increasing response rate include survey design and presentation, the inclusion of incentives, association with a trusted organisation
and staged follow up of respondents. Proposed strategies to maximise response rate are outlined in Table 6-6

**Table 6-6: Proposed strategies to maximise response rate**

<table>
<thead>
<tr>
<th>Identified reasons for nonresponse</th>
<th>Proposed strategy to address nonresponse</th>
</tr>
</thead>
</table>
| Time and survey length            | • Survey logic was incorporated into survey to limit the number of questions to 15 per respondent  
                                     | • Mean completion time for survey was 8 minutes based on pilot results |
| Perceived benefit                 | • Target sample frame to surgeons who perform ACLR and would benefit from the findings  
                                     | • Include an incentive to participate in order to enhance the perceived benefit |
| Confidentiality                   | • Provide details of ethical approval for conducting the study and include confidentiality statement |
| Question bias and inadequate responses | • The validation and reliability process is expected to limit question bias and ensure all appropriate response categories are provided |
| Credibility                       | • Ensure all correspondence is branded with the University of Queensland as a recognised and credible research institute  
                                     | • Seek endorsement from the AOA and AKS as recognised professional bodies  
                                     | • Design the survey in a way that is professional and relevant to the sample frame |
| Follow up                         | • Provide follow up emails at two and four weeks post initial contact to encourage participation |

### 6.3 Summary

Through the application of an evidence-based framework, a systematic approach was undertaken to develop a survey on graft tensioning practices. Rigorous steps were taken to ensure that the survey aims and population were clearly defined to guide survey design and ensure the data collected was relevant and accurate. Piloting of the instrument demonstrated the necessary validity and reliability to ensure a stable instrument. Clear mechanisms were put in place to ensure response rate is maximised and appropriate sample frame achieved.
This chapter contributes to the thesis by exploring current clinical practice with respect to graft tensioning and the opinions and beliefs that drive surgical decision-making regarding this topic. With a lack of empirical evidence dictating best practice a national survey was employed to undertake qualitative analysis of orthopaedic surgeons currently performing ACLR in Australia.

The chapter is adapted with minor additions and alterations to formatting to maintain consistency of the thesis from the following publication:

7.1 Abstract

Purpose
The application of graft tension during anterior cruciate ligament reconstruction is considered an important factor in achieving a successful outcome. However, due to a lack of evidence to guide clinical practice, many surgeons rely on clinical experience and tacit knowledge to determine an optimal tensioning protocol. As a result, wide variation exists in relation to graft tensioning practice limiting the ability to determine best practice. Thus, the primary aim of this study was to describe current clinical practice among Australian orthopaedic surgeons with respect to graft tensioning and explore the factors that influence practice.

Material and Methods
A survey was developed to address the aims of the study and pilot testing was completed to confirm validity and reliability. The survey population was defined as Australian orthopaedic surgeons, associated with the Australian Orthopaedic Association sub-specialty of knee, in order to target surgeons likely to perform ACLR. The final sampling frame consisted of 192 surgeons. To maximise response rate, the survey was distributed using various methods, follow up emails were sent at four and six weeks and a prize was offered as an incentive to participate.

Results
Eighty-three (43.2%) surgeons responded to the survey. The semitendinosus gracilis autograft was the primary graft selected (92.4%). Manual tensioning was the most common method (80.5%), with a maximum one-handed pull the most frequent description. The most frequently estimated tension ranged between 41N and 60N, with the knee positioned near full extension. Surgeons using a tensioning device tended to use a higher tension (mean 81.85N), with the knee positioned at 30 degrees flexion (40%). Fourteen surgeons (16.8%) reported they individualised tension to the patient based on viscoelasticity of the graft, graft diameter, patient anthropometry and age. Patient outcomes and available evidence were the primary factors reported to influence tensioning protocol; however, surgeons using a device were more influenced by accuracy while those using manual tension were more influenced by the surgical training they received.
Conclusion

Tensioning practices among Australian orthopaedic surgeons appear to consist of three main approaches. Firstly, manual tension using a sustained maximum one-handed pull, at an estimated tension of 41N to 60N, applied near full extension, using a semitendinosus gracilis autograft. Secondly, use of a tensioning device, applied at a mean tension of 81.85N, at 30 degrees knee flexion, using a semitendinosus gracilis autograft. Finally, an individual approach based on size and viscoelastic properties of the graft, patient anthropometry, contralateral comparison to the other knee and age of the patient.
7.2 Introduction

Knee instability and functional impairment are a hallmark of anterior cruciate ligament (ACL) rupture (Dargel et al., 2007; Ekdahl et al., 2008; Woo et al., 2006). Surgical reconstruction has proven effective in restoring stability, improving function and limiting the risk of further injury (Andersson et al., 2009; Biau et al., 2009; Lewis et al., 2008; Mohtadi et al., 2011). Numerous studies have demonstrated the benefit of anterior cruciate ligament reconstruction (ACLR) on outcomes such as arthrometry, limb symmetry and patient reported measures (Andersson et al., 2009; Biau et al., 2009; Lewis et al., 2008; Mohtadi et al., 2011). However, debate has emerged about the increased prevalence of degenerative changes post ACLR compared to conservative management (Delince & Ghafil, 2012; Kessler et al., 2008). Limitations in the ability of surgery to replicate the native ACL and restore normal biomechanics are thought to contribute to this increased risk of osteoarthritis (Delince & Ghafil, 2012; Kessler et al., 2008).

The application of tension to the graft prior to tibial fixation aims to replicate the femur-graft-tibia complex of the native ACL (Boylan et al., 2003; Heis & Paulos, 2002; Sherman et al., 2012). Assuming that an ideal graft has been selected and the tunnels positioned optimally, ensuring optimal tension of the graft is thought to contribute to the restoration of normal joint biomechanics (Sherman et al., 2012). However, what constitutes optimal graft tension has received little attention (Arneja et al., 2009; Kirwan et al., 2013). Anecdotally, too little tension is thought to result in less than ideal joint stability while too much tension is considered to place excessive stress on the graft and other joint structures (Boylan et al., 2003; Sherman et al., 2012).

Clinical trials investigating tension have used forces ranging from 20N to 147N with both bone-patella tendon-bone (BPTB) or semitendinosus gracilis (STG) autografts (Fleming et al., 2013; Kim et al., 2006; Nicholas et al., 2004; van Kampen et al., 1998; Yasuda et al., 1997; Yoshiya et al., 2002). A recent systematic review of clinical trials demonstrated an initial graft tension of 79N – 90N resulted in reduced side-to-side difference in anterior laxity when compared to tensions <79N or >90N (Kirwan et al., 2013). However, there was insufficient evidence to conclude whether patient specific function or long term outcome was better at any particular tension.

In the presence of limited clinical trials, a number of authors have attempted to define optimal tension from clinical experts. In 1996 the second European Society of Sports Traumatology, Knee
Surgery, and Arthroscopy (ESSKA) workshop recommended that graft tension occurs at 11 degrees of knee flexion with a tension of 47N for BPTB and 70N for STG grafts (Amis & Jakob, 1998). Furthermore, Cunningham et al. (2002) measured the actual amount of manual tension (MT) applied by 13 orthopaedic surgeons during ACLR using a STG graft and found tension ranged from 32N to 160N with a mean (SD) tension of 65.8(32)N. While differences in the amount of tension were observed, the study did not explore the reasons for such variation (Cunningham et al., 2002). More recently, McRae et al. (2011) surveyed members of the Canadian Orthopaedic Association on the natural history and treatment of anterior cruciate ligament injury. A component of the survey investigated method of tensioning with 81.6% of respondents electing to use MT rather than a tensioning device (TD). However, surgeons performing the most surgeries per annum were significantly more likely to use a tensioning device (p=0.018) than those performing few surgeries. Again, the study did not indicate the amount of tension applied or elucidate the reasons for the method selected (McRae et al., 2011).

Clinically, it is logical to accept that tension will not be consistent in all circumstances based on factors such as viscoelastic properties of the graft and size of the graft (Burks & Leland, 1988). However, there remains a lack of information on the adequate tension required in various surgical scenarios. As a result, many surgeons appear to rely on clinical experience and tacit knowledge to determine an optimal tensioning protocol. This appears to have led to wide variation in the methods and amount of graft tensioning reported in the literature and inhibites the ability to determine best practice. Thus, the primary aim of this study was to describe current clinical practice among Australian orthopaedic surgeons with respect to graft tensioning and explore the factors that influence practice.

7.3 Methodology

A survey was designed to collect data on current clinical practice and the influencing factors associated with graft tensioning. The University of Queensland Human Ethics Committee granted ethical approval prior to the research commencing in July 2014.

Survey Design
The survey was developed using an iterative process to establish validity and reliability (Aday & Cornelius, 2006; Czaja & Blair, 2005; Dillman, 1978; Jackson & Furnham, 2000). First, six orthopaedic surgeons were interviewed to determine themes around graft tensioning. Following
A number of factors were taken into consideration to maximize the response rate as previously published surveys of orthopaedic surgeons have reported poor response rates (Asch, Jedrziewski, & Christakis, 1997; Beebe et al., 2010; Bonevski, Magin, Horton, Foster, & Girgis, 2011). The final survey was limited to a maximum of 31 questions with mainly closed, dichotomous or scaled responses to limit survey length and complexity, which has been associated with higher response rates (Griffith, Cook, Guyatt, & Charles, 1999; VanGeest et al., 2007). The opportunity to win a prize was offered to recipients as an incentive to participate as this has also been demonstrated to enhance response rate (Kellerman & Herold, 2001; VanGeest et al., 2007).

**Sampling frame**
Recruitment was limited to surgeons practicing in Australia who identified with a sub-specialty of knee as defined by the Australian Orthopaedic Association (AOA). Details were obtained through publicly available methods including the ‘AOA find a surgeon’ function available on the website www.aoa.org.au and filtered by sub-specialty knee (n=251); the Australian Knee Society (AKS) website www.kneesociety.org.au (n=49); and, a general Internet search on the basis of a sub-specialty in knee (n=63). Of the 363 names identified by the three search strategies, 112 were duplicates, 34 did not have complete contact details, and 25 were identified as associate members or international members and were removed. The final sampling frame consisted of 192 orthopaedic surgeons likely to perform ACLR. Although it would have been ideal to have direct access to the accurate and comprehensive information held by the AOA or the Australian Health Practitioner Regulation Agency (AHPRA), confidentiality and privacy policy prevented such access. It was, therefore, necessary to rely on publicly available data to develop an appropriate sampling frame.
**Survey Distribution**

Three modes of survey distribution were utilised to increase participation. First, participants were emailed a link to the online survey. Second, the secretary of the AKS distributed an email link to encourage participation among AKS members. Third, flyers containing the link to the online survey were mailed to selected facilities where identified surgeons were known to practice. These three methods were used to improve the response rate of the identified sample (Heywood, Mudge, Ring, & Sansonfisher, 1995; Kellerman & Herold, 2001; VanGeest et al., 2007). Follow up emails were sent at four and six weeks post initial contact (Kellerman & Herold, 2001).

**Statistical Analysis**

To meet the aims of the study, frequencies and descriptive statistics were reported to identify current practice and factors influencing practice in ACLR. Frequencies with percentages were used for nominal and categorical data and descriptive statistics with mean (SD) were applied for continuous data. Statistical analysis was completed using SPSS 21.0 software package® (SPSS Inc., Chicago, IL, USA) and graphical representations were completed using Microsoft Excel® v2011 for Mac (Microsoft Corporation, Redmond WA).

### 7.4 Results

**Demographic data**

One hundred and ninety-two orthopaedic surgeons within Australia received the survey with 83 (43.2%) electing to participate. Four (4.8%) of the 83 respondents who commenced the survey did not complete all required questions. Demographic data is presented in Table 7-1. The final sample included orthopaedic surgeons from seven of the eight Australian states in both metropolitan and regional areas. The sample ranged in experience from less than five years to greater than 20 years, with 20 years experience (n=33) and more than 50 ACLR surgeries per year (n=36) the most frequently selected response.
Table 7-1: Survey population demographic data

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Frequency</th>
<th>Percent</th>
<th>Cumulative percent</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary place of practice</strong></td>
<td>79</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>QLD</td>
<td>31</td>
<td>39.24</td>
<td>39.24</td>
<td></td>
</tr>
<tr>
<td>NSW</td>
<td>18</td>
<td>22.78</td>
<td>62.02</td>
<td></td>
</tr>
<tr>
<td>ACT</td>
<td>2</td>
<td>2.53</td>
<td>64.55</td>
<td></td>
</tr>
<tr>
<td>VIC</td>
<td>14</td>
<td>17.72</td>
<td>82.27</td>
<td></td>
</tr>
<tr>
<td>TAS</td>
<td>2</td>
<td>2.53</td>
<td>84.8</td>
<td></td>
</tr>
<tr>
<td>SA</td>
<td>6</td>
<td>7.59</td>
<td>92.39</td>
<td></td>
</tr>
<tr>
<td>WA</td>
<td>6</td>
<td>7.59</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td><strong>Geographical setting</strong></td>
<td>79</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Metro</td>
<td>61</td>
<td>77.2</td>
<td>77.2</td>
<td></td>
</tr>
<tr>
<td>Regional</td>
<td>18</td>
<td>22.8</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>Rural</td>
<td>0</td>
<td>0</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td><strong>Years Experience</strong></td>
<td>79</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;5</td>
<td>8</td>
<td>10.1</td>
<td>10.1</td>
<td></td>
</tr>
<tr>
<td>5-9</td>
<td>13</td>
<td>16.5</td>
<td>26.6</td>
<td></td>
</tr>
<tr>
<td>10-14</td>
<td>15</td>
<td>19.0</td>
<td>45.6</td>
<td></td>
</tr>
<tr>
<td>15-19</td>
<td>10</td>
<td>12.7</td>
<td>58.2</td>
<td></td>
</tr>
<tr>
<td>&gt;20</td>
<td>33</td>
<td>41.8</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td><strong>Average ACL per year</strong></td>
<td>79</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;10</td>
<td>5</td>
<td>6.3</td>
<td>6.3</td>
<td></td>
</tr>
<tr>
<td>10-20</td>
<td>8</td>
<td>10.1</td>
<td>16.5</td>
<td></td>
</tr>
<tr>
<td>21-30</td>
<td>16</td>
<td>20.3</td>
<td>36.7</td>
<td></td>
</tr>
<tr>
<td>31-40</td>
<td>8</td>
<td>10.1</td>
<td>46.8</td>
<td></td>
</tr>
<tr>
<td>41-50</td>
<td>6</td>
<td>7.6</td>
<td>54.4</td>
<td></td>
</tr>
<tr>
<td>&gt;50</td>
<td>36</td>
<td>45.6</td>
<td>100</td>
<td></td>
</tr>
</tbody>
</table>

**Current clinical practice**

Sixty-six (80.5%) surgeons selected MT as their preferred method of tensioning with 92.4% reporting a preference for the STG autograft. The most common description for the amount of MT applied was a sustained maximum one-handed pull (51.5%), followed by a submaximal one-handed pull (31.8%). The remaining 16.7% provided their own description of manual tension with sensory feedback and range of motion (ROM) guiding the amount of tension applied {Table 7-2}. 
### Table 7-2: Identified descriptors for manual tensioning

<table>
<thead>
<tr>
<th>Description</th>
<th>Theme</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximal manual tension through 10 knee cycles</td>
<td>Knee ROM</td>
</tr>
<tr>
<td>Around 60 Newton Hand pull according to ESSKA recommendation</td>
<td>Estimated tension</td>
</tr>
<tr>
<td>Pull down and fix graft. No specific tensioning</td>
<td>Sensory feedback</td>
</tr>
<tr>
<td>I pull the graft through, secure it in the femur, pull distally and secure</td>
<td>Sensory feedback</td>
</tr>
<tr>
<td>The assistant tensions the graft using pliers manually levered against the</td>
<td>Visual guide</td>
</tr>
<tr>
<td>anterior tibia causing a temporary indentation in the skin</td>
<td></td>
</tr>
<tr>
<td>Maximal pull with ROM</td>
<td>Knee ROM</td>
</tr>
<tr>
<td>“Just right” pull while cycling the knee</td>
<td>Sensory feedback</td>
</tr>
<tr>
<td>Knee position and isometry of the graft</td>
<td>Isometry</td>
</tr>
<tr>
<td>Sustained pull by operator whilst assistant ranges knee at least 10 times</td>
<td>Knee ROM</td>
</tr>
<tr>
<td>Cycled through 10 range of movements with sustained one handed pull</td>
<td>Knee ROM</td>
</tr>
<tr>
<td>Tension tibial end rolled over artery forceps at tibial tunnel entrance and</td>
<td>Knee ROM</td>
</tr>
<tr>
<td>cycling knee up to 10 times negating tendon creep</td>
<td></td>
</tr>
</tbody>
</table>

ROM – Range of motion, ESSKA – European Society of Sports Traumatology, Knee Surgery and Arthroscopy

Fifty-two (78.7%) surgeons reported aiming for a standard amount of tension in all patients with 46.2% estimating the tension to be between 41N and 60N [Figure 7-1]. Fourteen surgeons reported individualising tension, with viscoelastic properties of the graft identified as the primary factor influencing variation between patients (64.3%). Other factors included graft diameter (42.9%), patient anthropometry (42.9%), stability in comparison to the contra-lateral knee (35.7%) and age of the patient (14.3%).
The most common angle of knee flexion during tensioning was near full extension (38.5%), followed by 30 degrees (21.5%) and 90 degrees (18.5%) [Table 7-3]. From the open responses, tensioning at terminal extension equal to the contralateral knee was also identified as a method by a small number of surgeons. Sixty percent (60%) of surgeons who estimated a higher tension (>80N) were more likely to tension at 30 or 90 degrees and 45% of surgeons estimating 41N to 60N tensioned near full extension.

**Table 7-3: Angle of flexion during graft tensioning**

<table>
<thead>
<tr>
<th>Angle of knee flexion during tension</th>
<th>N</th>
<th>Frequency</th>
<th>Percent</th>
<th>Cumulative Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>MT</td>
<td>TD</td>
<td>MT</td>
<td>TD</td>
</tr>
<tr>
<td>Full extension</td>
<td>65</td>
<td>15</td>
<td>7</td>
<td>2</td>
</tr>
<tr>
<td>Near full extension</td>
<td>25</td>
<td>4</td>
<td>8.5</td>
<td>26.7</td>
</tr>
<tr>
<td>30 degrees</td>
<td>14</td>
<td>6</td>
<td>21.5</td>
<td>40.0</td>
</tr>
<tr>
<td>60 degrees</td>
<td>3</td>
<td>0</td>
<td>4.6</td>
<td>0</td>
</tr>
<tr>
<td>90 degrees</td>
<td>12</td>
<td>3</td>
<td>18.5</td>
<td>20</td>
</tr>
<tr>
<td>Other</td>
<td>4</td>
<td>0</td>
<td>6.2</td>
<td>0</td>
</tr>
</tbody>
</table>
Sixteen (19.5%) surgeons selected the TD as their preferred option with all using the STG autograft. The mean (SD) force applied to the whole graft was 81.85N (29.56) with a range from 25N to 133N [Figure 7-1]. All surgeons using the TD standardised the amount of tension for all patients. The most common angle of knee flexion during tensioning was 30 degrees (40%) with near full extension (26.7%), 90 degrees (20%) and full extension (13.3%) also reported [Table 7-3]. Seventy-seven percent (77%) of surgeons tensioning at greater than 79N tensioned the graft at 30 or 90 degrees and 100% of surgeons using less than 79N tensioned near full extension.

*Factors influencing clinical practice*

The strongest influence for determining method of tensioning was the patient outcome achieved by the selected method. Available evidence was also reported as having some influence for both groups [Figure 7-2]. Factors related to the surgical procedure were reported to have little influence on the tensioning method selected. The MT group tended to report surgical training as a strong influencing factor compared to the TD group, who cited accuracy as a greater influence for selection of tensioning method. Overall, surgical opinion reported that tension was very important in restoring stability (67.5%) and function (62.7%) post ACLR with only 3.6% responding as not important.

*Figure 7-2: Factors influencing method of tensioning*
7.5 Discussion

The aim of the study was to define current clinical practice with respect to graft tensioning among Australian orthopaedic surgeons and identify factors influencing practice. Based on the findings of the survey, the most commonly described tensioning protocol was MT (80.5%), applied with a sustained maximum one-handed pull (51.5%), at an estimated tension of 41N to 60N (46.2%), applied near full extension (38.5%), using a STG autograft (92.4%). The previous outcomes achieved by the surgeon using their preferred method were the strongest factor influencing ongoing clinical practice (72.3%) while available evidence, surgical training and accuracy provided some influence.

Of the few clinical studies investigating graft tension and outcomes post ACLR, most have primarily focused on the optimal amount of tension to restore normal anterior-posterior (AP) stability and biomechanics of the knee (Fleming et al., 2013; Kim et al., 2006; Nicholas et al., 2004; van Kampen et al., 1998; Yasuda et al., 1997; Yoshiya et al., 2002). The results of such studies have been conflicting and suggest that acceptable outcomes can be achieved with tensions ranging from 20N to 147.1N (Arneja et al., 2009; Kirwan et al., 2013). Therefore, it is unsurprising that the range of tensions identified by a clinical population ranged from <20N to >133N. However, the application of tension needs to be considered more broadly than the force alone.

In the absence of clinical trials, cadaver and biomechanical studies have provided recommendations to guide tensioning practices based on the interaction between graft stiffness and the length-tension relationship of the reconstructed graft (Burks & Leland, 1988; Bylski-Austrow et al., 1990; Fleming et al., 2013). Burks and Leland (1988) demonstrated the inverse relationship between graft stiffness and the force required to restore stability in ACLR. With the BPTB autograft approximately twice as stiff as the STG autograft, less force would be required to restore stability and biomechanics when compared to the STG autograft (Pena et al., 2005; Suggs, Wang, & Li, 2003). Furthermore, cadaver based studies have also demonstrated that, depending on tunnel placement, the graft will lengthen to varying degrees as it nears extension, significantly increasing tension on the graft (Boylan et al., 2003; Bylski-Austrow et al., 1990; Fleming, Beynnon, Howe, McLeod, & Pope, 1992; Gertel et al., 1993; Lubowitz, 2014). As a result, the force required to restore anterior-posterior (AP) is directly related to the properties of the graft selected, the placement of the tunnel and the angle at which tension is applied. (Gertel et al., 1993; Lubowitz, 2014).
Based on the clinical practice identified within this study, the majority of surgeons (86.8%) used higher tensions (40N - >100N) for STG autograft compared to BPTB autograft (<20N - 60N). Surgeons who applied tension at 30 or 90 degrees tended to use >79N of force compared to <79N when tensioning near full extension, indicating that the biomechanical principles presented above and the findings of cadaver-based studies guide clinical practice for tensioning. Therefore, manipulation of graft type, amount of tension and angle of flexion allow a range of tensioning protocols to achieve a stable and functional joint.

Studies investigating the relationship between graft properties and biomechanics have postulated that even small changes in tunnel position and individual knee properties will influence the graft length tension relationship (Arnold et al., 2005; Lewis, 1998). Based on the principle of Hooke’s Law, as viscoelasticity and size of the graft change so too would the stiffness and, hence, the force required to restore AP stability and biomechanics (Giuliodori, Lujan, Briggs, Palani, & DiCarlo, 2009). Clinically, however, results of trials investigating such factors on patient outcome post ACL are conflicting and have failed to demonstrate clear benefits to patient function and outcome (Kamien, Hydrick, Replogle, Go, & Barrett, 2013; Mariscalco et al., 2013). Although the evidence is not clear, it is an important consideration to note that a one size fits all model may not apply for graft tensioning. This sentiment was observed within the current study, with 16.8% of respondents reporting an individualised approach to tensioning protocol. Factors such viscoelastic properties of the graft (64.3%), graft diameter (42.9%), patient anthropometry (42.9%), comparison to the contralateral knee (35.71%) and age of the patient (14.3%) were all considered important in determining the tensioning protocol. Interestingly, this group tended to be more experienced (>15 years) and performed more surgeries per year (>40), potentially indicating a greater level of clinical expertise guiding decision-making on tensioning protocol.

Based on the findings of this study, it was clear that graft tensioning was considered important in the restoration of stability and function post ACLR (96.4%). In the absence of consensus in the literature, the study investigated other factors influencing methods of tensioning. The strongest influence for all surgeons was the perceived patient outcomes achieved retrospectively by the surgeon. However, interpreting such information was difficult as there were no clinical measurements to quantify or define such outcomes. In addition to outcomes, available evidence was also reported as having some influence in determining tensioning protocol, suggesting that cadaver based studies, biomechanical models and clinical experience provide the evidence for practice in the absence of high quality clinical trials [Figure 7-2].
There was an observed difference between the MT and TD groups with respect to influences on practice. Respondents using a TD indicated accuracy as more influential compared to those using MT where the orthopaedic training was rated as more influential. Although definitively interpreting this information is not possible, it may indicate that surgeons who elect to use a TD make an active choice based on a belief that application of a specific tension will improve outcomes. In comparison, continuing with a MT method may be based on the ongoing success achieved with respect to patient outcomes indicating no need for change until supported by adequate evidence. However, until such clear evidence to indicate the optimal tensioning protocol is available, both approaches appear equally valid and effective.

Interestingly, the preference for the STG autograft was overwhelming among Australian orthopaedic surgeons. Similar studies by McRae et al. (2011) and Chechik et al. (2013) reported preferences for the STG autograft as 73% and 63% respectively, which is considerably lower than the findings of the current study. Unfortunately, it is not clear from the results why such a bias towards the STG autograft was identified among the sample population. However, historical trends have shown a growing preference in the STG autograft with studies from Mirza et al. (2000) and Marx, Jones, Angel, Wickiewicz, and Warren (2003) reported 32% and 12% respectively compared to 73% and 63% reported by McRae et al. (2011) and Chechik et al. (2013). Therefore, the current results may be a result of continued growth in preference for the STG autograft. Alternatively, the findings may be a result of regional variation secondary to other factors such as surgical training. Studies investigating clinical practice across geographical regions have shown similar variations in graft choice across various countries (Chechik et al., 2013). Importantly, due to the relationship between graft choice and tensioning, the findings in of the current study will primarily relate to the STG autograft.

The current survey received a response rate of 43.3%; comparable to other literature investigating ACLR. In nine identified studies, response rate ranged from 36% to 80% with a mean (SD) of 55.6%(14.8) (Brattwall, Jacobson, Forssblad, & Jakobsson, 2010; Erickson et al., 2014; Feller, Cooper, & Webster, 2002; Hiemstra, Veale, & Sasyiniuk, 2006; Kapoor et al., 2004; Marx et al., 2003; McRae et al., 2011; Mirza et al., 2000; Petersen & Zantop, 2013). This would indicate the survey methodology was effective in achieving an acceptable response rate. Furthermore, demographic data demonstrated distribution across regions in Australia with a majority of respondents reporting greater than 20 years experience and performing more than 50 ACLR per year, indicating clinical expertise in the area of ACLR (Table 7-1). Hence, the study provides an
insight into current clinical practice within Australia and highlights the factors influencing clinical practice related to graft tensioning in ACLR.

A limitation of the study was that the sampling frame was not representative of all orthopaedic surgeons performing ACLR within Australia. Due to the limitations in accessing accurate and complete contact details, surgeons not publicly listed were excluded from the sample. Furthermore, by targeting surgeons specialising in the knee, respondents tended to be more experienced and perform a greater number of procedures per year. As a result, clinical practice among inexperienced surgeons or those performing few ACLR procedures per year may not be represented by the current study. Finally, as the sample was limited to Australian orthopaedic surgeons, it does not account for variation that may exist in other countries. There have been minimal studies published investigating tensioning practices, which limits the ability to compare findings. However, McRae et al. (2011) reported 81.6% of Canadian orthopaedic surgeons used MT; similar to the findings of this study. In contrast, most Canadian respondents applied tension at 30 degrees knee flexion compared to near full extension based on an Australian sample. No data on amount of tension was reported. In addition to the limitations associated with sampling frame, the data collected on the force applied during manual tension was only an estimate based on surgical opinion. Although this is not an accurate representation of clinical practice, it was considered a reasonable estimation as it represents intended practice for which practitioners were aiming to achieve. This may indicate that, if they were measuring tension they would apply the estimated amount.

7.6 Conclusion

Tensioning practices appear among Australian orthopaedic surgeons appear to be categorised into three main approaches based on the results of this study. The first and most prevalent consists of applying MT, using a sustained maximum one-handed pull, at an estimated tension of 41N to 60N, applied near full extension, using a STG autograft. The second approach involves tensioning with a device at a mean tension of 81.85N, applied at 30 degrees knee flexion, using a STG autograft. Finally, tensioning is individualised based on patient specific factors including size and viscoelastic properties of the graft, patient anthropometry, contralateral comparison to the other knee and age of the patient. The combination of graft, tunnel placement and angle of knee flexion must be considered by the surgeon when determining the best approach for graft tensioning. In order to influence future practice, further research needs to be conducted to determine if there is any benefit
of one approach to tensioning over another with respect to patient outcomes in both the short and long term.
8 Discussion

The overarching goal of this thesis was to investigate ACL graft tensioning and its effect on patient outcomes post ACLR. In order to address the goal, three studies were conducted. Study one was a systematic review to determine the optimal amount of graft tension, which is required to restore patient function (chapter 3). Study two was a randomised controlled trial that compared the effect of two common methods for tensioning the ACL graft on functional outcomes 12 months post ACLR (chapter 5). Study three was an observational cross sectional survey of Australian orthopaedic surgeons to identify current tensioning practices, perceived patient outcomes and factors influencing clinical practice (chapter 7). A synopsis of the important findings from each study is presented in Table 8-1.
Table 8-1: Synopsis of primary thesis results

<table>
<thead>
<tr>
<th>Chapter</th>
<th>Content</th>
<th>Findings</th>
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| Chapter 3: Initial graft tension and the effect on postoperative patient functional outcomes in anterior cruciate ligament reconstruction (Kirwan et al., 2013) | A systematic review of available literature comparing the amount of tension applied to the graft and functional outcomes post ACLR                                                                 | • A trend towards medium tension (79N – 90N) resulted in less STSD in anterior tibial displacement when compared to low and high tension.  
• The effect on function was unable to be established  
• Insufficient homogeneity between studies prohibited meta-analysis  
• Poor methodological quality |
| Chapter 5: Does graft tensioning method during anterior cruciate ligament reconstruction affect long term patient outcomes: A randomised controlled trial | A randomised controlled trial comparing a manual tensioning protocol with that of a tensioning device on patient function up to 12 months post ACLR                                                                 | • No difference between MT and the use of a TD on patient function or laxity at 12 months post ACLR.                                                                                                    |
| Chapter 7: Graft tensioning practices in anterior cruciate ligament reconstruction among orthopaedic surgeons in Australia: A national survey | Investigate current clinical practice among Australian orthopaedic surgeons with respect to graft tensioning and explore the factors that influence practice.                                                   | • Surgeons deemed tension as very important in ACLR.  
• Three main approaches to graft tension were identified.  
1. MT with a sustained maximum one-handed pull, applied near full extension  
2. TD at a mean tension of 81.85N, applied at 30 degrees knee flexion  
3. Individualised approach based on size and viscoelasticity of graft, patient anthropometry, comparison to the contralateral limb and age  
• There is variability in tensioning protocols between Australian orthopaedic surgeons.  
• Experience and patient outcomes provide the greatest influence on choice of tensioning protocol |

ACLR – anterior cruciate ligament reconstruction; MT – manual tension; TD – Tensioning device; STG – Semitendinosus gracilis; STSD – Side-to-side difference
8.1 Contribution of the thesis to the body of evidence

This thesis offers original and novel information on graft tensioning outcomes that provides an evidence base for future clinical practice. Study one was the first published study to quantitatively summarise clinical trials and demonstrated that a graft tension between 79N and 90N reduces STSD in AP laxity when compared to tensions <79N or >90N. However, there was insufficient evidence to determine the effect of tension on functional outcomes. This synthesis of evidence provides a guide for orthopaedic surgeons with respect to the optimal force required during graft tensioning to minimise STSD in AP laxity. Study two was the first study to directly compare the effect that two methods of tensioning had on functional outcomes post ACLR. Conclusions drawn from the RCT suggest that a MT or TD method, performed by an experienced orthopaedic surgeon effectively restores patient function 12 months post ACLR. Based on the findings presented in study two, surgeons can confidently select either method of tensioning dependent upon personal and surgical factors such as ease of application, impact on surgery time or the availability of surgical assistance. Study three involved the development of a valid and reliable survey of Australian orthopaedic surgeons investigating current practice and perceptions about graft tension. The findings, based on a robust response rate (43.2%), suggest that tensioning practice among Australian orthopaedic surgeons is dependent on graft material, method and knee angle during tensioning. Three common methods of tensioning were identified by the survey, with patient outcomes and research evidence identified as key factors influencing the chosen method. It was also observed that surgical training was a strong influence on selecting a manual method compared to ‘accuracy’ in those electing to tension with a device. As this was the first study to comprehensively evaluate current practices in graft tensioning, the results provide valuable insight into the clinical rationale for graft tensioning methods in light of available evidence.

8.2 The relationship between graft tension and patient outcomes

The overall findings of the thesis suggest that an optimal tension to best restore patient function post ACLR was unable to be determined. However, a medium tension (79N to 90N) appears to result in a reduced STSD in anterior tibial displacement when compared to low (<79N) and high (>90N) tension (Kirwan et al., 2013). No difference was observed between patient functional outcomes when comparing tensioning with a device at 80N and a manual method of tensioning using a sustained maximum one-handed pull at one-year post surgery. The perceptions of
Australian orthopaedic surgeons (study three) were, in most part, consistent with the empirical findings presented in the thesis. However, there was a perception that graft tension was clinically important in restoring patient function, which was not identified by the thesis.

The observed difference between the impact that tension has on STSD in anterior tibial translation and patient function presents an interesting picture that is supported by the literature. For example, a number of studies have reported poor correlation between measures of laxity and patient function (Eastlack et al., 1999; Hrubesch et al., 2000; Kocher et al., 2004; Risberg, Holm, Tjomsland, et al., 1999; Snyder-Mackler et al., 1997). Other studies suggest that function is only affected once laxity becomes excessive (Ageberg, Roberts, Holmstrom, & Friden, 2005; Sernert et al., 2002). A possible explanation for such a variation in the literature may be related to the proposed difference between the term laxity and instability (Needle et al., 2014; Schmitt, Fitzgerald, Reisman, & Rudolph, 2008).

Commonly, laxity infers a STSD in anterior tibial translation as opposed to instability, which refers more specifically to the patient’s experience of ‘giving way’ during functional activities (Needle et al., 2014). In addition to laxity, it is hypothesised that, under dynamic functional conditions, impaired muscle strength, neuromuscular control, proprioception and psychological factors all contribute to a sense of instability and, hence, a loss of function (Eastlack et al., 1999; Needle et al., 2014; Schmitt et al., 2008). Sernert et al. (2002) found that, when STSD in anterior tibial translation was greater than 6mm a significantly poorer outcome resulted based on the IKDC, Lysholm, Tegner and hop test. Similarly, a study by Ageberg et al. (2005) demonstrated that balance and proprioception were also impaired in ACL deficient knees where the mean AP laxity exceeded 6mm. Therefore, it may be suggested that, as laxity increases beyond 6mm of anterior tibial translation, the incidence of patient reported instability is more likely; thus, resulting in impaired function.

Assuming that a STSD difference in AP laxity of ≥6mm impairs function, the results from studies one and two suggest that, regardless of the amount or method, tension alone is unlikely to result in greater than 6mm of AP laxity. Clinical trials have reported a mean (SD) STSD in anterior tibial displacement, which varies between 0.6(1.7)mm and 3.9(2.2)mm for tensions ranging from 20N to 147.1N, which is below the 6mm threshold reported by Sernert et al. (2002). Similarly, biomechanical studies by Pena et al. (2005) and Boylan et al. (2003) demonstrated that laxity varied between 1.1mm to 2.9mm when tension differed between 20N to 68N. Therefore, it is reasonable to suggest that, if a tension of between 20N and 147.1N is applied to the graft, then AP laxity is unlikely to exceed the 6mm with no functional impairment resulting. In order for AP laxity to
exceed 6mm, it is likely that a combination of other factors such as tunnel placement, graft selection or fixation method would be required to contribute to the outcome.

An alternative interpretation of the results is that the sensitivity of the patient reported and clinical measures used to determine function and the length of follow up used in the studies may have been insufficient to establish a definitive relationship between tension and function. It is possible that a change in AP laxity of less than 6mm may result in subtle changes to knee biomechanics or function, which are not manifested as global functional deficits, such as climbing stairs or hopping, as identified by the patient or the clinician. Furthermore, the potential changes associated with tension may not appear within two years of surgery. For example, studies investigating the development of degenerative joint disease typically report follow up periods of between 5 and 15 years (Frobell et al., 2013; Kessler et al., 2008; Meuffels et al., 2009; Meunier et al., 2007). Therefore, future research may need to consider how function is measured when determining the impact of tensioning as well as the inclusion of mid to long term follow up. Sophisticated techniques such as biomechanical analysis may also be necessary to detect joint level changes that may influence short or long-term functional outcomes post ACLR.

Despite the fact that the relationship between tension and patient function remains elusive, there appears to be a clearer relationship between tension and STSD in anterior tibial displacement. The relationship between the amount of tension and the restoration of stability is unsurprising when biomechanical principles are considered. If the ACL substitute is considered an elastic material, then, based on Hooke’s Law, \( F = -kX \) (where \( F \) is the tension applied to the graft, \( k \) is the graft constant which is proportional to length and cross sectional area and \( X \) is the amount of stretch exhibited by the graft), as the tensile force increases, the graft will elongate proportional to its length and cross sectional area (CSA), resulting in an increase in graft stiffness (Giuliodori et al., 2009). This means that, as the graft becomes stiffer, the AP translation will reduce; however, physiologically, there is likely to be a point when AP stability is optimally restored.

The systematic review suggested that, as tension increased from 20N to 90N, STSD in anterior tibial displacement decreased; however, beyond 90N, STSD in anterior tibial displacement once again increased. A number of biomechanical studies investigating tension have recorded a similar relationship between tension and STSD in anterior tibial displacement. Boylan et al. (2003) demonstrated that, as tension increased from 23N to 68N, AP laxity reduced from 8.9mm to 6mm when using a STG graft harvested from 18 fresh-frozen cadavers. Pena et al. (2005) demonstrated a reduction of between 1.1mm to 1.5mm when tension increased from 20N to 60N in a finite element
Furthermore, Numazaki, Tohyama, Nakano, Kikuchi, and Yasuda (2002) found that, as tension increased from 80N to 140N, using a soft tissue porcine graft fixed with a bioscrew, the stiffness of the femur-graft-tibia complex decreased. This reduction in stiffness would likely result in an increase in AP laxity, resulting in a lack of biomechanical or clinical benefit to a tension beyond 80N. Importantly, cadaver studies, finite element modelling and animal studies have also warned that, as tension increases beyond the recommended level, the risk of increased TF compression forces, posterior subluxation of the tibia, impaired ROM and poor revascularisation of the graft are heightened. Such complications may result in impaired function, an increased risk of graft failure and greater incidence of degenerative joint changes (Burks & Leland, 1988; Bylski-Austrow et al., 1990; Fleming et al., 2013; Yoshiya et al., 1987).

A conclusion that can be drawn from the thesis findings in conjunction with the supporting literature is that a range of tensions can be applied in order to deliver a successful outcome for the patient. A tension between 79N and 90N will best restore STSD in anterior tibial displacement while an acceptable patient functional outcome can be achieved with a tension between 20N and 90N. Furthermore, there appears to be no clinical or biomechanics benefit to applying a tension beyond 90N and, based on the proposed risks, should not be advocated. It is also important to recognise that, although STSD in anterior tibial displacement appears to decrease as tension increases from 20N to 80N, it is not clear if the effect is clinically important in relation to patient outcomes; thus, limiting the ability to draw conclusive judgment on the benefits between such tensions.

### 8.3 The art of applying tension

In determining the optimal tension for restoring both stability and function, a number of interrelated surgical and non-surgical variables must be considered. Balancing such factors to determine what tension between 20N and 90N will achieve the best outcome for the patient requires the expertise of the surgeon. In the absence of clear evidence guiding the interaction between each variable, there is an element of surgical ‘art’ that is required to achieve an optimal outcome. Through experience and training, surgeons will refine and enhance their skills through manipulating one or more variables to apply the optimal amount of tension. As evidenced by the findings in study three, slight variations in multiple surgical and non-surgical factors can be applied, which ultimately achieve the same outcome. However, an understanding of the effect that each variable has on tension is necessary for success.
Surgical considerations

Graft type influences the amount of tension applied due to its biomechanical properties. It is well recognised that the two most common substitutes used in ACLR are the BPTB and STG autografts as supported by the literature as well as the results reported in study three (Chechik et al., 2013; Mahnik et al., 2013; McRae et al., 2011). The BPTB autograft exhibits properties that are between two and four times stiffer than the STG autograft, indicating that less force is required to regain AP stability in the BPTB autograft when compared to the STG (Burks & Leland, 1988; Hamner, Brown, Steiner, Hecker, & Hayes, 1999; Noyes, Butler, Grood, Zernicke, & Hefzy, 1984; Suggs et al., 2003). Clinical studies by Yoshiya et al. (2002) and van Kampen et al. (1998) advocated for low tension (20N – 25N) when using a BPTB autograft. While, Kim et al. (2006) and Yasuda et al. (1997) suggested a medium tension (78.5N – 80N) when using a STG autograft, supporting the notion that less tension should be applied in high stiffness material. Results from study three confirmed that surgeons using a BPTB autograft tended to apply less tension (estimated maximum 60N) compared to those using the STG autograft (maximum of 133N). Similarly, the report published by Amis and Jakob (1998) from the ESSKA congress reported the average clinical practice for tensioning of the BPTB autograft to be a force of 47N compared to 70N for the STG autograft.

Another important consideration affecting graft tension is graft length. As the length of the graft increases, the structural stiffness reduces, meaning a longer graft will lengthen at a greater rate per unit of force when compared to a shorter graft (Suggs et al., 2003); therefore, greater tension is required to achieve the same amount of stiffness. The length of the graft is ultimately determined by tunnel position and the fixation method. Currently, the anatomic non-isometric tunnel position is recognised as the most common; however, as discussed in chapter two, variability remains in the exact placement of the tunnel within the ACL footprint, which may result in small changes to graft length and, thus, require different amounts of graft tension. Furthermore, an aperture fixation, which is applied at the level of the joint, will create a shorter graft when compared to suspensory fixation, which is applied distal to the joint, further influencing the amount of tension required (Harvey et al., 2005).

The anatomic non-isometric placement will also result in a graft lengthening and tightening as the knee approaches full extension. Lubowitz et al. (2014) demonstrated that the substituted ACL graft could lengthen up to 6.7mm when the knee is moved from flexion to extension. Such changes in length will result in an increased graft stiffness as the knee extends, reducing the amount of tension.
required to restore AP laxity at that angle of flexion (Lubowitz, 2014). Therefore, the amount of
graft tension required to restore AP stability in full extension may be less when compared to 30
degrees of flexion (Austin et al., 2007; Lubowitz, 2014). The findings reported in study three
indicate that knee position is considered important when applying graft tension. Surgeons using
tensions greater than 79N were more likely to tension at 30 degrees of knee flexion compared to
surgeons using less than 79N who tensioned at less than 30 degrees. However, the extent to which a
change in knee position will affect the amount of tension necessary to achieve the same outcome is
unclear based on clinical opinion and biomechanical studies.

Furthermore, the stiffness of the substitute graft will progressively deteriorate over time dependent
The rate of decline is primarily dependent on the combination of fixation device and the graft
material, which need to be considered by the surgeon (Eagar, Hull, & Howell, 2004; Hapa &
Barber, 2009; Liu-Barba, Howell, & Hull, 2007). For example, a study by Grover et al. (2005)
reported that intra-articular tension of the graft reduced by 64% post cyclic loading when using an
interference screw compared to 100% with double staples, 50% with a spiked washer and 56% with
the WasherLoc™. Therefore, it may be necessary to apply a higher tension when using double
staples compared to the spiked washer in order to account for the known loss of tension post
fixation.

Non-surgical considerations
In addition to surgical factors, the amount of tension applied may also be influenced by non-
surgical factors such as the patient’s age, anthropometry, gender and stability of the contra-lateral
knee as supported by the findings presented in study three. Attributes such as height, body mass
index (BMI) and thigh circumference have been positively correlated to graft CSA (Beyzadeoglu,
Akgun, Tasdelen, & Karahan, 2012; Conte, Hyatt, Gatt, & Dhawan, 2014; Tuman et al., 2007).
Furthermore, it is recognised that age and gender may affect the stiffness and tensile properties of
human tendon (Blackburn, Bell, Norcross, Hudson, & Kimsey, 2009; Sobolewski, Ryan,
Thompson, McHugh, & Conchola, 2014). As a result, the tension necessary to restore AP stability
may vary based on individual presentations.

In the quest to restore the patient’s natural biomechanics, a surgeon may apply a tension aimed to
match the unaffected joint. Survey findings presented in study three highlighted that a small number
of surgeons apply an amount of tension that intra-operatively restores STSD in anterior tibial
translation equal to the unaffected limb. This method is similar to that posed by Fleming et al.
(2013) who demonstrated a similar outcome when applying a laxity based tensioning protocol compared to a quantified tension. It would be reasonable to suggest, however, that, although laxity determined the tension in this study, the two variables are inherently related and, thus, likely to result in the same outcome. However, it further highlights the types of variations that can be applied to achieve the same result.

The combination of surgical and non-surgical variables plays an important role in determining the amount of tension necessary to restore AP stability and patient function. As a result, no single amount of tension can be recommended. Therefore, the clinical expertise of the surgeon is essential to balance the interaction between each factor to achieve the desired outcome. For example, a low stiffness STG autograft tensioned in 30 degrees of flexion with a low stiffness indirect fixation, in an older short female, would likely require greater tension when compared to a high stiffness BPTB autograft fixed with a high stiffness direct fixation in full extension, on a young tall male.

8.4 Is a tensioning device necessary to achieve the desired tension

The method of applying tensioning appears to have no effect on patient outcome based on the results of study two. The lack of difference observed between the two tensioning methods indicates that both methods were effective at restoring STSD in anterior tibial translation and patient function within 12 months post surgery, based on the outcome measures selected. However, it must be considered that the surgeons participating in the study were both experienced in ACLR surgery (surgeon A, 10-14 years clinical experience and between 31 and 40 ACLR’s per year; Surgeon B, 10 – 14 years clinical experience and >50 ACLR’s per year). It could be hypothesised that had an inexperienced population of surgeons been included, the outcomes achieved between surgeons and method may have been different.

Based on the findings presented in study three, it is interesting to note that 81% of respondents preferred manual tensioning compared to a tensioning device. As a result, the amount of tension is often not quantified; thus, it is difficult to determine conclusively if a tension between 20N and 90N is applied to the graft. Data collected in study three suggests that, in the absence of a quantifiable tension, surgeons adopt other methods to guide the application of adequate tension. Cycling the knee repeatedly through full range of motion to exclude the presence of graft impingement or graft tightness and the administration of a Lachman’s test are common methods. As a result, the clinical risks associated with over or under tensioning are assessed and cleared, which suggests that an
appropriate amount of tension has been applied i.e. between 20N and 90N. Such methods have been supported by Fleming et al. (2013) who demonstrated effective outcomes through using a laxity based protocol for determining the appropriate amount of manual tension during ACLR.

It is still important to consider the risk of applying excessive or insufficient tension when using a manual method. Studies conducted by O'Neill et al. (2011) and Cunningham et al. (2002) investigated the amount of tension applied by orthopaedic surgeons under blinded conditions. The results from both studies demonstrated that tension ranged from as little as 8.7N to as much as 160N based on 18 different orthopaedic surgeons. Importantly, the mean (SD) from each study was 20.8N(5.1) and 65.8N(32) respectively, which is within the recommended tension range. However, the low and high tensions were well outside the ideal range. Interestingly, neither study asked the surgeon to estimate the amount of tension they applied. Therefore, it is impossible to know if the low and high tensions were intentional or a result of an unreliable method. Regardless, it is an important consideration for surgical practice and the question must be asked whether surgical training should include the use of a tensioning device to help ‘calibrate’ the force applied by an inexperienced surgeon. In conjunction with assessing ROM and stability intra-operatively, an understanding of the approximate amount of tension applied would only aid in optimising the patient outcome.

Significantly, the amount of tension applied in clinical practice among Australian orthopaedic surgeons tended to agree with the evidence. Eighty-eight percent of surgeons undertaking manual tensioning estimated their tension to be between 20N and 100N, with most reporting between 41N and 60N and those using a tensioning device applied a mean (SD) of 81.9N(29.6). In addition, less than 5% of respondents reported a tension outside of the recommended range. However, interpretation of the results associated with manual tension still needs to be considered with caution as this is merely an estimation and not indicative of actual tension. Although there is evidence that surgeons undertaking manual methods of tensioning utilise other techniques to ensure appropriate tension is applied, the risk remains that, on occasions, insufficient or excessive tension may be applied, which may increase the risk of greater AP laxity.

It appears that clinical practice is consistent with current evidence and the findings of the thesis. Although the manual method is widely used and appears to provide appropriate outcomes, there is an argument that the use of a tensioning device, particularly during training, may reduce the risk of applying excessive or insufficient tension during ACLR.
8.5 Methodological limitations

Systematic review (study one)
Studies included within the systematic review lacked the homogeneity necessary to perform meta-analysis. Variations in the type of functional outcome measures used in each study were the primary factors limiting the ability to conduct meta-analysis. Furthermore, data was unavailable at certain time points for the included studies. The corresponding author from each study was contacted to request unpublished data; however, no additional data was provided. As a result, quantitative analysis for certain tensions was not available.

Randomised controlled trial (study two)
This study achieved a score of 8 out of 12 based on the Methodology Quality Assessment Score utilised in study two (Bourke et al., 2010). The study’s strengths included clear concealment of allocation, clear inclusion criteria, standardisation of protocols and appropriate blinding of assessors. However, a number of limitations associated with the study must be recognised.

First, the randomised controlled trial sample size was not determined statistically to reach a desired level of power. In order to achieve a power of 0.80 (alpha = 0.05) based on the primary outcome measures (IKDC), 23 participants per group were needed. In addition, to determine a significant difference in STSD in anterior tibial displacement, post hoc analysis suggested, to achieve a power 0.80 (alpha = 0.05) a sample of 297 participants per group would be required to detect a 1mm difference. This would require a large-scale multicentre trial with significant funding, which was beyond the scope of this thesis. Furthermore, this study was conducted in the public health service, which only performs approximately 40% of ACLR in Australia with the remaining 60% performed in the private sector (Orchard, 2009). Therefore, future studies should include private health facilities for recruitment.

The functional outcome measures included were based on recognised validity, reliability and industry acceptance. However, based on the fact that tensioning primarily affected stability, the IKDC, Lysholm, Tegner and SLHD may not be sensitive to the effect that small changes in STSD in AP laxity has on function up to 12 months post surgery.

Participant follow up was limited to 12 months, which is insufficient to determine the long-term effects of graft tension on function. A graft tensioned either insufficiently or excessively is proposed to increase the risk of degenerative joint changes. Although it is difficult to predict when
such changes may appear, imaging studies investigating joint changes tend to be a minimum of 36 months. Long-term studies are necessary to determine the effect of graft tensioning on incidence of OA (Fleming et al., 2013).

The amount of manual tension was not measured intra-operatively due to the impact on operation time and associated costs. As a result, there is no assurance that similar tension was applied to participants in both groups. Furthermore, as the same surgeons were completing MT and TD, familiarisation with the application of a set tension may have influenced their manual force. Future studies comparing MT and TD methods should consider collecting force data in a blinded manner to account for such a possibility.

In conducting a randomised controlled trial, factors other than the method of tensioning were standardised. However, the placement of the tibial and femoral tunnels requires surgeons to interpret a relatively subjective description of tunnel placement. Although both surgeons were experienced in ACLR, studies have shown that tunnel angle and placement in the anatomical footprint can vary between surgeons (Picard et al., 2001; Rue, Ghodadra, & Bach, 2008). Small changes in tunnel angle and placement have been associated with knee laxity, limitations in ROM and poorer outcomes, and methods to ensure standardisation should be employed in the future.

National survey (study three)
The survey response rate was 43.3% and the sample frame was based on publicly available data and, hence, not representative of the whole population of orthopaedic surgeons conducting ACLR. Results presented may be sensitive to sampling and non-response error. However, the response rate is similar to other studies surveying an orthopaedic population (Erickson et al., 2014; McRae et al., 2011) and demographic data for respondents was comparable to available workforce data suggesting non-response error did not bias the findings (RACS, 2011).

Data presented on the force applied during manual tensioning was based on an estimate and, therefore, may not represent actual clinical practice. Respondents were given the choice to answer this question in an attempt to only capture data from surgeons who feel confident to make such an estimate. Furthermore, it was assumed that their estimation represented a belief as to how much tension should be applied and, hence, if tension was measured, this would be their desired goal.
8.6 Future direction

Evidence based practice represents a paradigm that requires rigorous assessment of the evidence to guide decision-making but also recognises the importance of clinical expertise and the individual patient needs for best practice (Prasad, 2013). Future trials investigating the effect of tensioning on patient outcomes must consider the philosophy of evidence based practice and incorporate the many factors that relate to graft tension and influence patient outcome. Therefore, studies investigating the interaction between graft type, graft size, individual patient biology, tunnel placement, fixation methods and knee angle with graft tension will be better placed to provide a comprehensive conclusion on what is optimal tension during ACLR. It was previously highlighted that determining optimal tension is multifactorial. Therefore, knowledge of the effect that one factor has on the amount of tension will provide a more scientific approach to graft tensioning. For example, understanding the rate at which the amount of tension needs to decrease for every 1mm increase in graft diameter to achieve an optimal result would be beneficial. This notion was supported by the interest generated by study one, prompting a letter to the editor from Sorel, van de Graaf, and Mutsaerts (2014) (Appendix N). The letter proposes similar views on the need for a better understanding of how graft size and tension correlate to achieve the desired outcome.

However, in order to conduct such a multivariate trial, a randomised controlled methodology would be complex and it would be difficult to control all variables. Therefore, alternative methodologies are better placed for such research. A long term, large scale epidemiological approach would provide an excellent platform to investigate the interaction of such factors with tension. Conducting such a trial, however, would require significant change to clinical practice. Findings in study three suggest that the majority of surgeons in Australia do not record the amount of tension and, therefore, would be excluded from the study, which could result in significant bias in the study results. Alternatively, surgeons would need to agree to change practice and record tension over a period of time to collect the relevant data in order to deliver conclusive evidence to guide tensioning practices. It would be fair to suggest that the most effective way to conduct such a trial would be the establishment of a national ACL register in which the aforementioned factors were recorded along with patient outcomes. Again, this would require a change in practice for surgeons not currently collecting tension. Based on the Swedish (www.xbase.nu) and UK (www.uknlr.co.uk) registries it appears that this has not been done elsewhere as neither database includes any information pertaining to graft tension. A likely explanation for the lack of inclusion to date is the perception that a tensioning device may be unreliable in accurately predicting intra-articular graft
tension. Furthermore, methods that more accurately measure intra-articular graft tension, such as the insertion of length and tension transducers into the graft may not be clinically viable.

A novel approach to investigating the relationship between tension and patient outcome may be to investigate graft elongation as opposed to force. As previously discussed, the principles of Hooke’s Law demonstrate that the amount of displacement experienced by an elastic material is linear to the force applied where the rate of change is relative to the stiffness of the material. Therefore, if the aim of applying graft tension is to restore AP stability and function by minimising viscoelastic creep and increasing stiffness, then measuring elongation may provide a more effective way of determining optimal force. The undertaking of preliminary biomechanical studies that plot the force displacement curve of STG autografts relative to CSA and length, which are commonly measured intra-operatively, may provide a guide for clinical practice. Therefore, the amount of elongation could be measured relative to the position of the graft within the tibial tunnel, which may negate the need for a tensioning device. However, the validity and efficacy of such an approach is theoretical and would require further research.

Conclusions

The application of between 20N and 90N of tension is successful at restoring patient function while minimising the risk of complications associated with over or under constraining the knee. Furthermore, the application of between 79N and 90N appears to better restore STSD in anterior tibial displacement. The method by which the surgeon applies the tension does not appear to affect patient outcomes within the first 12 months when applied by an experienced surgeon and other strategies such as assessing range and stability intra-operatively may provide a sound alternative to quantifying tension. Current clinical practice suggests that less than 5% of Australian orthopaedic surgeons are not applying the recommended tension during ACLR indicating that, based on current evidence, changes to practice are not currently necessary.
References


eT4w4UQAu4M86JKcYcIoImln0eINJqXzbbaEHg2X1B4mBiKKhFZpjPZX9fxQ_P1
mB7r9X655s8PQNYyOuTQKhpFcXiHyjO2SCBeLJF1K5WnTvIlMxAjBzhvC-
uMwBFnhKB9I8efrvvzn6z2Kx0


Appendix A  KT-1000 Standard Application

Setting up the patient:

Patient positioned supine on plinth with head and feet supported, hands over midsection and eyes looking at the ceiling. Place the thigh support platform under both legs at a level proximal to the popliteal space. Then place the foot support platform under both feet with heel adjacent to lateral supports and distal to the lateral malleolus.

NB: If this causes excessive internal rotation of the knee then place the heel X cm from the lateral support as measured by the ruler located on the foot support platform.

Ensure that the knee is flexed to between 20° and 35° and if not then adjust the height of the thigh support platform to achieve this. Place the Velcro thigh strap around the thighs proximal to the knee to hold the hip in a neutral position.

Fitting the KT100:

- Place arthrometer on anterior tibia (of the non-involved side first and then test the involved) and align the joint line arrow with the joint line of the knee.
- Apply the distal Velcro strap and a comfortable tightness for the patient.
- Align the patella stabiliser over the patella so that the patella is positioned in the trochlear groove.
- Check joint line arrow is aligned and ensure patella in desired position and securely apply the proximal Velcro strap.
- Oscillate the calf anterior/posterior ensuring the arthrometer needle is moving freely to ensure patient is relaxed.
- Place hand on patella pad to stabilise the patella and apply posterior force until there is no movement on the dial.
- Pull on the force handle and 3 tones will sound at 15lb, 20lb, and 30lb and the same will occur when you push on the force handle.
- Repeatedly pull and push only to the 1st tone until the dial returns to the same spot. Then rotate the dial so that the needle aligns with zero.
Testing the ACL:

- Maintain posterior pressure on the patella reference pad and push the force handle until it reaches the 20lb tone then release.
- Rotate the dial to align with zero and repeat until the needle returns to zero 3 times.
- Maintain the patella pad pressure and ask the patient to gently and slowly try and raise the heel off the foot support.
- Record the displacement on the data collection sheet. Then apply a momentary 20lb posterior push on the force handle and the dial should return to zero +/- 0.5mm.
- Then perform the maximum displacement test by stabilising the patella and applying a direct manual force to the back of the calf proximal to the Velcro strap and record the measurement on the dial.
- Repeat for the involved knee
Appendix B  Ethical approval – RCT

THE UNIVERSITY OF QUEENSLAND
Institutional Approval Form For Experiments On Humans
Including Behavioural Research

Chief Investigator:  Mr Garry Kirwan
Project Title:  An Evaluation Of The Clinical Outcomes Of Manually Tensioned ACL Reconstructions Compared To Those Tensioned With A Tensioning Device
Supervisor:  Dr Trevor Russell, Dr Lucy Chipchase
Co-Investigator(s):  Dr Philip Dalton, Dr Mark Dekkers, Mr Michael Bourke
Department(s):  School of Health and Rehabilitation Sciences
Project Number:  201.0000458
Granting Agency/Degree:  MPhil
Duration:  10th April 2011

Comments:
Expedited review on the basis of approval from the Princess Alexandra Hospital HREC, dated 20/12/2006.

Name of responsible Committee:–
Medical Research Ethics Committee
This project complies with the provisions contained in the National Statement on Ethical Conduct in Human Research and complies with the regulations governing experimentation on humans.

Name of Ethics Committee representative:–
Dr Dennis Taaffe
Deputy Chairperson
Medical Research Ethics Committee

Date:  19/04/2000  Signature:  [Signature]

153
Mr Michael Bourke  
Physiotherapy Department  
Queen Elizabeth II Hospital  
Private Mail Bag 2  
ACACIA RIDGE QLD 4110

Dear Mr Bourke 

Re: 2006/072  
An evaluation of the clinical outcomes of manually tensioned ACL reconstructions compared to those tensioned with a tensioning device.  
ACL tensioning research.

On the 15 December 2006 the Princess Alexandra Hospital Human Research Ethics Committee Chair/executively reviewed the following amendment(s) for the above study and approval was granted:

- Participant Information Sheet and Consent Form, dated 7 December 2006;  
- Modified Lysholm Score.

It should be noted that all requirements of the original approval still apply.

If you have any queries, please do not hesitate to contact the Princess Alexandra Hospital Human Research Ethics Committee Executive Support Officer on (07) 3240 7672.

Best wishes for the progress of the study.

Yours sincerely  

Ms Gwyneth Petrie  
Chair  
Human Research Ethics Committee  
Princess Alexandra Hospital Health Service District

Office  
Princess Alexandra Hospital  
Health Service District  
Postal  
Ipswich Road  
Woolloongabba Q 4102  
Phone  
61 7 3240 2111  
Fax  
61 7 3240 6677
### Appendix C  Participant consent form - RCT

![Queensland Government](https://example.com/logo)

**CONSENT FORM FOR PARTICIPATION IN STUDY**

**QEII JUBILEE HOSPITAL**

**PROJECT TITLE**  
*An evaluation of the clinical outcomes of manually tensioned ACL reconstructions compared to those tensioned with a tensioning device*

**LAY TITLE**  
The effectiveness of tensioning an ACL graft with a tensioning device as oppose to the surgeon manually tensioning the graft

<table>
<thead>
<tr>
<th>INVESTIGATORS</th>
<th>Role</th>
</tr>
</thead>
<tbody>
<tr>
<td>Michael Bourke</td>
<td>Senior Physiotherapist – Orthopedics, QEII Jubilee Hospital</td>
</tr>
<tr>
<td>Garry Kirwan</td>
<td>Physiotherapist, QEII Jubilee Hospital</td>
</tr>
<tr>
<td>Dr Philip Dalton</td>
<td>Director of Orthopaedic Surgery, QEII Jubilee Hospital</td>
</tr>
<tr>
<td>Dr Mark Dekkers</td>
<td>Asst. Director of Orthopaedics, Princess Alexandra Hospital</td>
</tr>
<tr>
<td>Dr Trevor Russell</td>
<td>Senior Lecturer, University of Qld</td>
</tr>
<tr>
<td>Dr Lucy Chipchase</td>
<td>Senior Lecturer, University of Qld</td>
</tr>
</tbody>
</table>

I ____________________________ *(print name)* consent to take part in the above study.

I have read the attached Participant Information Sheet. I understand the nature and purpose of this randomised study and any side-effects or risks involved. All my questions have been answered to my satisfaction.

I acknowledge that my involvement in the study may not be of benefit to me.

The opportunity has been given to me to have a friend or relative present when the study was explained.

I understand that taking part in the study is voluntary and I am free to withdraw at any time I wish and this will not affect my clinical management.

I understand that all the information gained in the study (e.g. Lysholm Score) will be treated confidentially.

I give permission for the research team to access my medical record.

Participant Name: _____________________________ Signature: _____________________________ Date: ___/___/___

Witness Name: _____________________________ Signature: _____________________________ Date: ___/___/___

I have explained the nature and purpose of this study to the above participant and have answered their questions.

Investigating Surgeon: _____________________________ Date: ___/___/___
### PROJECT TITLE
An evaluation of the clinical outcomes of manually tensioned ACL reconstructions compared to those tensioned with a tensioning device

### LAY TITLE
Does using a tensioning device make a difference to ACL surgery outcomes?

### INVESTIGATORS
All members of the research team are contactable on 07 3275 6331 where they may be paged by reception staff. The after hours contact is 073275 6111. Michael Bourke’s direct contact number is 073275 6173.

- **Michael Bourke**  
  Senior Physiotherapist – Orthopedics, QEII Jubilee Hospital

- **Garry Kirwan**  
  Physiotherapist, QEII Jubilee Hospital

- **Dr Philip Dalton**  
  Director of Orthopaedic Surgery, QEII Jubilee Hospital

- **Dr Mark Dekkers**  
  Asst. Director of Orthopaedics, Princess Alexandra Hospital

- **Dr Trevor Russell**  
  Senior Lecturer, University of Qld

- **Dr Lucy Chipchase**  
  Senior Lecturer, University of Qld

You have elected to have an anterior cruciate ligament (ACL) reconstruction. This process involves preparation for surgery and rehabilitation after surgery. The rehabilitation phase of your recovery lasts 12 months. We would like your help in investigating the difference between two types of tensioning approaches to ACL reconstruction surgery which are both commonly used at QEII Jubilee Hospital. There are no risks involved in this study outside of the risks associated with routine ACL reconstruction surgery.

If you agree to participate in the study, you will be randomly assigned to one of two groups; like the toss of a coin. Group one will consist of participants having their ligament graft tensioned manually by the surgeon. Group two will consist of participants having their ligament graft tensioned with a tensioning device. Manual tensioning is the more common of these routine procedures. Manually tensioning an ACL graft involves the surgeon placing traction on the graft with his or her hands. The tensioning device simply applies and measures the tension. You will not be told which tensioning method you are having. This is important to ensure the study is impartial. Regardless of which group you are assigned to, you will undergo standard preparation and rehabilitation for your operation. Outside of ‘normal’ rehabilitation, you will be required to attend follow-up Physiotherapy appointments at QEII Jubilee Hospital at 3 months, 6 months and 12 months after your operation. At these follow-up appointments the Physiotherapists will measure your knee function and stability. All protocols and rehabilitation for your operation will be identical across both groups.

2/1/2015
The assessments at 3 months, 6 months and 12 months will involve a combination of the following:

1. Questions about your ability to function will be asked (including the Lysholm Score)
2. ACL Graft tension testing using a standard tension testing device
3. Functional tests tailored to your ability

None of the assessments performed during the study will cause any pain beyond that normally encountered with physical knee assessment and rehabilitation after knee replacement.

**Alternatives to Participation in the Study**

Participation in this study is on a voluntary basis and you reserve the right to withdraw at any time from the study for any reason, without any penalty and without affecting any further treatment or relations with the QEII Jubilee Hospital. Should you elect not to participate in the study you will continue to follow the standard process for ACL reconstruction surgery. In discussion with your surgeon you can decide which type of surgery will be performed rather than being randomly allocated a type of surgery. In order for the researchers to accurately assess the effectiveness of your ACL reconstruction, we request that you continue with the prescribed exercises and physiotherapy treatment as instructed by your physiotherapist.

Total study withdrawal is not possible due to the type of procedure, but participants may wish to withdraw from follow-up study visits and use of their data for research.

**Confidentiality**

Your confidentiality will be maintained at all times throughout the study and you will in no way be identified in any publication or report. Furthermore, you will be assigned a number that will be used, rather than your name, on all stored information. All assessment measures will be stored in a lockable cabinet in the Physiotherapy Department at the QEII Jubilee Hospital. Data collected with computer technology will be stored in a password protected secure database in coded format and will be available only to those researchers directly involved in this research. De-identified data will be stored for a maximum of fifteen years upon completion of the study.

A copy of the outcomes of this study will be available from the Physiotherapy Department at the QEII Jubilee Hospital for your interest at the completion of the study in January 2012. Additionally, you are invited to attend QEII Physiotherapy Department on completion of the study where the results of the study will be available. The information gathered from this study will assist Orthopaedic Surgeons determine the most appropriate tensioning method for ACL reconstruction.

The QEII Jubilee Hospital ethics committee has given ethical clearance for this study. You are free to discuss your participation in this study with the project staff on 3275 6173, however, if you would like to speak to an officer not involved in the study, you may contact the Princess Alexandra Hospital Human Research Ethics Committee (acting for the QEII Jubilee Hospital) on 3240 5856 or the University of Queensland Ethics Committee on 3365 3924.

By consenting to participate in this study you give members of the research team permission to access your medical record for the purpose of the study. You also acknowledge that this study will provide no direct benefit to you.
ANTERIOR CRUCIATE LIGAMENT
RECONSTRUCTION

PATIENT INFORMATION AND REHABILITATION
MANAGEMENT GUIDELINES
2nd Edition

Produced by Tim Spalding, Consultant Orthopaedic Surgeon and
Mark Dekkers, Consultant Orthopaedic Surgeon in conjunction with
the departments of Physiotherapy and Rehabilitation at Hospital of St
Cross, Rugby; The Warwickshire Nuffield Hospital; and Coventry and
Warwickshire Hospital
General Principles for understanding the rehabilitation process

- **Exercises need to be done 4 – 5 times per day:** Little and often is better than an extensive overload period.

- **Pain, heat and increasing swelling in the knee are bad:** Any of these symptoms can mean that you may be overdoing exercises. It is unlikely that it indicates a serious problem but you should always call your physiotherapist to discuss any extreme pain, heat or increasing swelling within or around the knee.

- **The difference between good and bad pain:** After major knee surgery your knee will be sore. It is important to understand that discomfort is normal particularly when performing some of the stretching exercises. In addition, your knee may ache after an exercise session. This is expected and normal so long as it is not associated with any significant increase in swelling. ‘Bad pain’ is usually sharp and severe in nature. It may be brought on by pushing too hard and it may be accompanied by an increase in swelling. Activities causing such a problem should be stopped and advice sought from your physiotherapist.

Summary of Rehabilitation Phases

There are six main rehabilitation phases and example exercises for each phase are given in the sections that follow. There are many different exercises available to achieve the goals and these are tailored to each individual by the physiotherapy team. Various example exercises are outlined in each section.

- Phase 1: Preoperative preparation/operative period
- Phase 2: Initial Post Op Phase: first 2 weeks
- Phase 3: Proprioception Phase: week 3 – 6
- Phase 4: Strength Phase: week 6 – 12
- Phase 5: Early Sport Training: month 3 – 6
- Phase 6: Return to Sport: month 6 – 9

You will be reviewed at the following times in outpatients and the goals for those stages are detailed in the guidelines:

- 2 weeks.
- 6 weeks.
- 3 months.
- 6 months.
- 1 year.
PHASE 1: PREOPERATIVE PREPARATION AND OPERATIVE PERIOD

Pre Op

Rehabilitation begins before surgery in the pre operative phase to ensure that you and your knee are ready for the operation.

- Ensure full range of movement, especially normal hyperextension.
- Exercises to maintain quadriceps and hamstring muscle strength.
- Advice session in physio department for familiarisation with post op exercises and hospital stay.

Operative Day

- Admitted on morning of day of surgery.
- Re-assessed and examined on the ward by the surgeon or member of surgical team – opportunity to ask questions.
- The consent form will be completed and your leg marked for the correct side.
- Outcome assessment questionnaires may be given to you to complete.
- At some stage a knee splint and a Cryo cuff (iced water compression device) will be supplied.

Pain Relief Following Surgery

There are several strategies to reduce the discomfort following surgery and these are constantly under re-evaluation in order to improve pain control. A separate information sheet is available outlining these strategies but essentially they include the following: nerve blocks which numb the leg for the first 12 – 18 hours, use of a knee splint to hold the leg straight for 24 – 48 hours reducing discomfort on movement, a Cryo cuff which is a cold water compression device to reduce swelling and pain, and anti-inflammatory painkillers and medication.

Initial Post Operative Period

You will be able to go home on the day of surgery or the first postoperative day after a night in hospital. This will need to be discussed with your surgical team.

Most patients stay overnight and start to move their knee on the morning after surgery under the instruction of the physiotherapist. If you opt to have surgery as a day case then you will be able to go home some 3 – 4 hours after the operation but you will need to return to hospital on the first or second day after surgery for the dressing to be removed and for instruction on early exercises.

On return from the operating theatre you will wake up with your leg held in a straight leg splint, which prevents the knee bending. A Cryo cuff (ice compression device) will be applied to the knee under the splint in order to keep the knee cool and reduce swelling. Sometimes a drain is seen emerging from the dressing, removing any bleeding from the wound.

The splint and dressings are removed on the 1st or 2nd postoperative day and you will then be instructed on crutches and on the exercises to perform for the first 2 weeks. Crutches are usually required for the first 2 weeks but full weight bearing is allowed.
Instructions on Discharge From Ward

The following is a list of instructions and expectations that you should receive before you leave the ward.

- Keep the wound dry for 3 days or until the wound has sealed.
- Clips or Stitches to be removed at 7 days by local GP or district nurse.
- Date given for review in clinic or on ward after 2 weeks.
- Date given for Outpatient physiotherapy appointment.
- Work Advice given: to expect to be able to return as follows:
  - Desk work at 3 – 4 weeks
  - Light manual work at 6 weeks
  - Heavy manual work (ladder work etc) at 3 – 4 months.
- Driving Advice given: To return to driving at 3 – 4 weeks depending on knee function.
- Instruction on use of Cryo cuff or ice packs to control swelling.

PHASE 2: INITIAL POST OP PHASE – FIRST 2 WEEKS

Aim

The aim of this phase is to regain range of movement and to allow the swelling in the knee to settle. The most important aim is to regain normal and full extension (straightening) of the knee. The physiotherapist usually sees you one week following surgery to add in extra exercises.

2-Week Review Goals

Range of motion: full terminal extension to 110° flexion.
Wound healed.
Minimal swelling in knee and around wound.
Normal gait pattern.
Independent leg control.

1st Week Exercises

- Extension exercises: Prone hangs (Fig 12) and Heel props (Fig 13). These are particularly important in order to prevent build up of scar tissue around the new graft.
- Static muscle exercises (quadriceps, gluteal contractions and hamstring exercises Figs 14, 15).
- Flexion exercises (knee bending): (Figs 16, 17, 18) active and passive movements over the edge of the bed using the other leg for support and small range of swinging action if possible. Increase using heel slides, side lying on the bed or wall slides (feet on the wall).
- Patella mobilisation exercises to prevent tethering of the patella in scar tissue (Fig 19).
- Mobilise weight bearing as tolerated using crutches.
- Control swelling with regular use of Cryo cuff or ice packs.
- Avoid active exercise with the leg unsupported (open chain exercise) from 30° flexion to full extension for the first 6 weeks.

**Fig. 12 Prone hangs**

Lie on stomach and allow knees to hang over edge of bed for 5 minutes.

**Fig. 13 Heel props**

Rest heel on rolled towel or 2 pillows so that knee is not supported. Allow your knee to straighten in this position for 10 minutes.

**Fig. 14 Static Quadriceps**

Sit or lie with leg out straight, tighten your thigh muscles and push knee down firmly against the bed. Hold and for 5 secs, repeat: 10 times.

**Fig. 15 Static Hamstrings**

Sit on bed or floor, bend your knee slightly, then push your heel into the bed keeping knee slightly bent. Hold for 5 secs. Repeat 10 times.
Fig. 16 Flexion exercises. Sliding board

Sitting or lying with sliding board under your leg. Bend knee by sliding foot towards your buttock. Repeat 10 times.

Fig. 17 Flexion exercises. Knee swings

Sit on chair, cross legs with operated leg on top. Allow knees to bend, supporting with the leg which is underneath, then straighten knees. Repeat 10 times.

Fig. 18 Flex exercises. Heel slide

Sit on chair with foot on floor, bend knee as far as possible. Repeat 10 times.
Fig. 19 Patella mobilisation

Stand or sit with leg straight, push kneecap outwards, then push towards opposite knee. Repeat 10 times.

Push kneecap towards foot, allow to return to position. Repeat 10 times.

2nd Week Additional Exercises (Figs 20 – 25)
- Hip extension by bridging.
- Static bike to full movement with minimal resistance.
- Physio ball sitting: rocking / wall / balance. Progress as required.
- Gait education weaning off crutches.
- Scar mobilisation if wound healed.
- Four planes of straight leg raising.
- Quarter squats (using crutches or a chair for support initially).

Fig. 20 Balance on one leg.

Stand on your operated leg with knee fully extended and locked, keeping your balance for 30 secs.
Fig. 21 Mini Squats

Stand with feet shoulder width apart, bend knees until they are over toes, then straighten knees. Repeat 10 times.

Fig. 22 Heel and toe raises

Standing, push up onto toes, then rock back onto heels. Repeat 10 times.

Fig. 23 Extension thrusts

Stand straight holding onto chair, bend knees slightly then straighten legs and push up onto toes. Repeat 10 times.

Fig. 24 Hamstring stretch

Stand with leg to be stretched on floor or on stool, pull toes towards you and lean forwards keeping leg straight, hold for 20 secs. Repeat 3 times each leg.
PHASE 3: PROPRIOCEPTION PHASE - WEEKS 3 – 6

Aim

The aim of this phase is to work on proprioceptive exercises and to develop light endurance and strength training. This stage is also important for developing core stability to provide the framework to progress to full active function. By the end of six weeks your knee should feel normal in activities of daily living.

6-Week Review Goals

Example Exercises

- Range of motion: active and passive, wall slides, heel slides on bed.
- Weight bearing: full weight bearing off crutches working to establish normal gait.
- Mini step ups and dips.
- Treadmill work: gradual increase in speed and gradient.
- Gym ball (bridging exercises).
- Start swimming (no breast stroke kick).
- Hamstring curls lying on the front using a lightweight or elastic cord resistance. (Delayed until 6 weeks if hamstring tendons used for the graft)
- Mini trampoline balance exercises.
- Rowing with low resistance.
- Outdoor cycling on the road tolerated once confidence achieved.
- Kneeling on a pillow or gym ball to desensitise the scar region.
- Static bike utilising gradual increase in resistance.

PHASE 4: STRENGTH PHASE - WEEKS 6 – 12

Aim

At six weeks the thigh muscle tone and definition (quadriceps / hamstrings) will be poor but the bone blocks on the patella tendon graft or the soft tissue hamstring graft will now have become solid within the femur and tibia tunnels such that more vigorous strength training can commence. Progress is monitored and controlled by the physiotherapist according to the speed of recovery of strength and control.

It is important to avoid too rapid progress, as there is a risk of developing overload complications.

3 Months Review Goals
No swelling
Full range of movement
Confident feeling of stability.

Example Exercises

- Start early jog training as control allows – on trampoline or treadmill.
- Gradually progress to treadmill running.
- Step exercises with increased height speed and weight.
- Step machine working at a steady level.
- Gait re-education drills: walking fast / slow, side, front and backward.
- Progress walking to change of direction.
- Slow walking backwards on the treadmill.
PHASE 5: EARLY SPORT TRAINING PHASE - MONTH 3 - 6

Aim
Pivoting and cutting manoeuvres are introduced at this stage, building up to light sport training. This involves a progressive programme of slow and moderate speed strength training and agility drills. Manual work should be possible within the restraints of the occupation. Exercises for power and agility training are introduced.

6 Months Review Goals
Functional and strength tests: 85% of normal side.
Return to non contact sports / training.

Month 3 Example Exercises
- Jog / run on the treadmill or on the pavement.
- Normal skipping introduced.
- Lunges with increased intensity and frequency.
- Hopping: both or single leg action. Also side to side as tolerated.
- Mini trampoline hopping.
- Running including gradual changes of pace plus acceleration/deceleration.
- Progress running through slow turns, figure of 8 turns, to tighter turns and cutting.

Months 4 - 6 Example Exercises
Hard pivoting and cutting is introduced at this stage providing stability/actory progress with running training.
- Functional testing (single leg hop test).
- Agility training: shuttle runs, ball dribbling and other sports drills promoted.
- Specific sports training aimed at the individual.
- At the six months stage ready for discharge from rehabilitation and return to non contact sport.
PHASE 6: RETURN TO SPORT PHASE - MONTH 6 – 9

Aim

The aim of this phase is to progress sport training and to develop strength/ endurance levels in order to establish a base for return to full sporting activity. This takes time, especially in building up confidence to progress to full contact activities. Return to contact sport is not recommended until strength and functional outcomes are measured at greater than 85% of the normal side.

The time to regain pre injury level of skill and performance is very variable but can take 3 – 4 months of training and playing.

Guidance from the physiotherapist in regaining confidence in a sport environment by modifying training and specific drills, can help with a quicker return to contact or full level sport competition.

- Sports specific skills training is introduced with club activities.
- Progress is best achieved in conjunction with a general fitness programme.
- Full contact is best avoided until you are able to tolerate a full training session and you are confident with your fitness and endurance.

Remember:

If you have any queries or if you require any advice regarding your knee or the rehabilitation programme please do not hesitate to call your physiotherapist.
Appendix F  
Linear mixed modelling – RCT 

Normal Q-Q plots, Histogram and line graphs of means for measured outcomes

International knee documentation committee score

Normal Q-Q Plot of IKDC Score

Mean IKDC Score

IKDC Score

Pre Surgery
2 weeks Post Surgery
3 months Post Surgery
6 months Post Surgery
12 months Post Surgery

Error bars: 95% CI

Tensioning Group
Manually Tensioned
Tensioning Device

Mean = 60.36  
Std. Dev. = 20.56  
N = 106
Lysholm score

Normal Q-Q Plot of Lysholm Score

Mean = 72.10  
Std. Dev. = 19.937  
N = 106

Tensioning Group
- Manually Tensioned
- Tensioning Device

Error bars: 95% CI

Assessment Point
- Pre-Surgery
- 2 weeks Post-Surgery
- 3 months Post-Surgery
- 4 months Post-Surgery
- 12 months Post-Surgery
KT-1000 STSD in anterior tibial displacement at 30 pounds
KT-1000 STSD in anterior tibial displacement manual maximum force
Single leg hop test for distance STSD
Appendix G  Ethics approval for national survey

30th June 2014

A/Prof Trevor Russell
Division of Physiotherapy
The University of Queensland

t.russell1@uq.edu.au

Dear Trevor

Re: Ethics application #2014SHRS002

I am pleased to advise that your project ‘Graft tensioning practices in anterior cruciate ligament reconstruction: A national survey of Australian orthopaedic surgeons’ (ethics#2014SHRSPTHY002) has been reviewed and cleared within the School of Health and Rehabilitation Sciences in accordance with the ethical review guidelines and processes of the University of Queensland.

Sincerely,

Professor Bill Vicenzino
Division of Physiotherapy Ethics Officer
e-mail: b.vicenzino@uq.edu.au
phone: 0409 267 247
**Appendix H  A National Survey - First draft**

General Information regarding survey

All questions relate to your PREFERRED approach to anterior cruciate ligament reconstruction (ACLR). We acknowledge that factors change based on a number of clinical presentations but we are interested in your preferred approach assuming ideal conditions.

Overall opinion on graft tensioning

1. In your general opinion how important is the amount of graft tension in relation to achieving the following outcomes:

<table>
<thead>
<tr>
<th></th>
<th>Not Important</th>
<th>Somewhat Important</th>
<th>Very Important</th>
</tr>
</thead>
<tbody>
<tr>
<td>Restoring anterior - posterior knee laxity</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Long term functional outcome</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

**PROCEED TO Q2**
Surgical Technique

2. What is your standard graft choice for ACLR?

☐ Semitendinosus Gracilis Autograft

☐ Semitendinosus Gracilis Allograft

☐ Bone Patella Tendon Bone Autograft

☐ Bone Patella Tendon Bone Allograft

☐ Synthetic

☐ Other

If other please describe:

3. Which of the following categories best describes your method of tensioning during ACLR?

☐ Manual hand pull Go to Q4

☐ Tensioning device Go to Q15
Manual Tensioning Method

The following questions explore how you approach the manual method and your opinion on the benefits of this approach

4. Which of the following descriptions of a manual method best describes how you apply tension during ACLR?

☐ Sustained maximum one-handed pull  
Go to Q5

☐ Sub maximal one-handed pull  
Go to Q5

☐ Amount of tension varies based on the patient  
Go to Q9

☐ Other  
Go to Q5

If other please specify:

5. Do you aim for a standard amount of tension for all patients?

☐ Yes  
Go to Q6

☐ No  
Go to Q9

6. In your opinion, are you able to estimate the amount of tension used?

☐ Yes  
Go to Q7

☐ No  
Go to Q8
7. Please estimate the amount of tension you apply (select the option which applies to your standard approach):

   a. Semitendinosus strand: ________________________________

   b. Gracilis strand: ________________________________

   c. Posterolateral bundle: ________________________________

   d. Anteromedial bundle: ________________________________

   e. Whole graft: ________________________________

     GO TO Q10

8. **How** do you standardise the tension?

     GO TO Q10

9. What factors influence the amount of tension you apply for each person? (You may select more than one)

   □ Graft diameter

   □ Patient anthropometry

   □ Viscoelastic properties of the graft

   □ Stability of the knee

   □ Other

   If other please specify:
10. At what knee angle do you apply graft tension prior to fixation?

☐ Full extension

☐ Near full extension

☐ 30° Flexion

☐ 60° Flexion

☐ 90° Flexion

☐ Other

If other please specify:

11. Have you ever trialled the use of a tensioning device?

☐ Yes

☐ No
12. Please rate how the following factors influence your decision to select a manual method:

<table>
<thead>
<tr>
<th>Factors</th>
<th>No Influence</th>
<th>Some Influence</th>
<th>Strong Influence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient outcomes achieved with this method</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Evaluation of available evidence</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>The need for an assistant to apply tension</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Impact of tensioning method on operation time</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>The implication of attaching a device to the Tibia</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Orthopaedic surgical training</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Cost of the tensioning device</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>The accuracy of the tensioning device</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

If there are other factors that influence your decision please specify:

**GO TO PAGE 11**
Tensioning Device Method

The following questions are exploring the technique you use for tensioning with a device and your opinion on the benefits of this approach.

13. What device do you prefer to use for tensioning?

14. Do you apply a standard amount of tension each time?
   - [ ] Yes  Go to Q15
   - [ ] No  Go to Q16

15. How much tension do you apply to the graft? (Only select the option which applies to your standard approach. Please indicate units of force, N/lbs)
   - a. Semitendinosus strand________________________
   - b. Gracilis strand______________________________
   - c. Posterolateral bundle________________________
   - d. Anteromedial bundle________________________
   - e. Whole graft________________________________

   **GO TO Q18**
16. Which factors influence the amount of tension you apply for each person? (You may select more than one)

- [ ] Graft diameter
- [ ] Patient anthropometry
- [ ] Viscoelastic properties of the graft
- [ ] Stability of the knee
- [ ] Other

If other please specify:

17. Please state the range of tensions you apply (Only answer the options which applies to your standard approach):

   a. Semitendinosus strand: ____________________________
   b. Gracilis strand: ____________________________
   c. Posterolateral bundle: ____________________________
   d. Anteromedial bundle: ____________________________
   e. Whole graft: ____________________________
18. At what knee angle do you apply graft tension prior to fixation?

☐ Full extension

☐ Near full extension

☐ 30° Flexion

☐ 60° Flexion

☐ 90° Flexion

☐ Other

If other please specify:

19. Have you trialled the manual method for graft tensioning?

☐ Yes

☐ No
20. Please rate how the following factors influence your decision to use a tensioning device:

<table>
<thead>
<tr>
<th>Factors</th>
<th>No Influence</th>
<th>Some Influence</th>
<th>Strong Influence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient outcomes achieved with this method</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Evaluation of available evidence</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>The need for an assistant to apply tension</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Impact of tensioning method on operation time</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>The implication of attaching a device to the Tibia</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Orthopaedic surgical training</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Cost of the tensioning device</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>The accuracy of the tensioning device</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

If there are other factors that influence your decision please specify:

PROCEED TO NEXT SECTION ON PAGE 11
Demographic Information:

Surname:______________________________________________________________________________

First name:____________________________________________________________________________

21. Please specify your primary area of practice:

☐ Metropolitan

☐ Regional

☐ Rural/remote

22. Years of experience as an orthopaedic surgeon.

☐ <5 years

☐ 5-9 years

☐ 10-14 years

☐ 15-19 years

☐ >20 years
23. On average how many ACLRs do you perform annually?

☐ < 10

☐ 10 - 20

☐ 21 - 30

☐ 31 - 40

☐ 41 – 50

☐ > 50

24. On average how long do you follow up your ACLR patients?

☐ < 3 months

☐ 3 – 5 months

☐ 6 – 8 months

☐ 9 – 11 months

☐ ≥ 12 months or longer
25. In your opinion how common are the following limitations long-term? (Question continued over page)

<table>
<thead>
<tr>
<th>Factors</th>
<th>Never</th>
<th>Uncommon</th>
<th>Common</th>
<th>Very Common</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anterior knee pain</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Patello-femoral Pain</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>General knee pain</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Lack of end of range flexion</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Lack of end of range extension</td>
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<tr>
<td>Reduced quadriceps strength</td>
<td>☐</td>
<td>☐</td>
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<td>☐</td>
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<td>Reduced hamstring strength</td>
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<td>☐</td>
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<td>Inability to return to previous level of function</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Graft failure</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

If there are any other limitations please specify:

SURVEY COMPLETE – Thank you for your time and thoughts on this topic it is greatly appreciated
Appendix I  A National Survey – Second draft

General Information regarding survey

All questions relate to your STANDARD approach to anterior cruciate ligament reconstruction (ACLR). We acknowledge that factors change based on a number of clinical presentations but we are interested in your standard approach assuming ideal conditions

Graft tension for the purpose of this survey refers specifically to the process where tension is applied to the graft prior to tibial fixation. It DOES NOT relate to the process where tension is applied during pre-conditioning and preparation of the graft

Overall opinion on graft tensioning

1. In your general opinion how important is the amount of graft tension in relation to achieving the following outcomes:

<table>
<thead>
<tr>
<th></th>
<th>Not Important</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Restoring anterior - posterior knee stability</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>Long term functional outcome</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
</tbody>
</table>

PROCEED TO Q2
Surgical Technique

2. What is your standard graft choice for ACLR?

☐ Semitendinosus Gracilis Autograft

☐ Semitendinosus Gracilis Allograft

☐ Bone Patella Tendon Bone Autograft

☐ Bone Patella Tendon Bone Allograft

☐ Synthetic

☐ Other

If other please describe:

3. Which of the following categories best describes your standard method of tensioning during ACLR?

☐ Manual hand pull Go to Q4

☐ Tensioning device Go to Q13
Manual Tensioning Method

The following questions explore how you approach the manual method and your opinion on the benefits of this approach.

4. Which of the following descriptions of a manual method best describes how you apply tension during ACLR?

☐ Sustained maximum one-handed pull

☐ Sub maximal one-handed pull

☐ Other

If other please specify:

5. Do you aim for a standard amount of tension for all patients?

☐ Yes Go to Q6

☐ No Go to Q9

6. In your opinion, are you able to estimate the amount of tension applied?

☐ Yes Go to Q7

☐ No Go to Q8
7. How much tension would you estimate is produced manually to the whole graft?

☐ < 20N (<5lb)

☐ 20N – 40N (5 – 8lb)

☐ 41N – 60N (9 – 13lb)

☐ 61N – 80N (14 – 17lb)

☐ 81N – 100N (18 – 22lb)

☐ > 100N (>22lb)

**GO TO Q10**

8. **How** do you standardise the amount of tension?

**GO TO Q10**

9. What factors influence the amount of tension you apply for each person? (You may select more than one)

☐ Graft diameter

☐ Patient anthropometry

☐ Viscoelastic properties of the graft

☐ Stability of the knee

☐ Other

If other please specify:

**PROCEED TO Q10**
10. At what knee angle do you apply graft tension prior to fixation?

☐ Full hyperextension

☐ Near full extension

☐ 30° Flexion

☐ 60° Flexion

☐ 90° Flexion

☐ Other

If other please specify:

11. Have you ever trialled the use of a tensioning device?

☐ Yes

☐ No
12. Please rate how the following factors influence your decision to select a manual method:

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<tr>
<td>The implication of attaching a device to the Tibia</td>
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<td></td>
<td></td>
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<tr>
<td>Orthopaedic surgical training</td>
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<tr>
<td>Cost of method</td>
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<tr>
<td>Sensory feedback from manual pull</td>
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<td></td>
</tr>
</tbody>
</table>

If there are other factors that influence your decision please specify:

GO TO TOP OF PAGE 11
Tensioning Device Method

The following question are exploring the technique you use for tensioning with a device and your opinion on the benefits of this approach

13. What device do you prefer to use for tensioning?

14. Do you apply a standard amount of tension each time?
   □ Yes  Go to Q15
   □ No   Go to Q16

15. How much tension do you apply to the graft? (Only select the option which applies to your standard approach. Please indicate units of force, N/lbs)
   a. Semitendinosus strand_____________________
   b. Gracilis strand____________________________
   c. Posterolateral bundle_____________________
   d. Anteromedial bundle_____________________
   e. Whole graft_________________________________

   GO TO Q18
16. Which factors influence the amount of tension you apply for each person? (You may select more than one)

☐ Graft diameter

☐ Patient anthropometry

☐ Viscoelastic properties of the graft

☐ Stability of the knee

☐ Other

If other please specify:

17. Please state the minimum and maximum amount of tension you would apply e.g 20N-80N would imply 20N is the minimum and 80N is the maximum applied to a strand based on the factors identified in the previous question (Only answer the option that applies to your standard approach)

a. Semitendinosus strand: _________________________

b. Gracilis strand: ______________________________

c. Posterolateral bundle: _______________________

d. Anteromedial bundle: _______________________

e. Whole graft: ________________________________

PROCEED TO Q18
18. At what knee angle do you apply graft tension prior to fixation?

☐ Full hyperextension

☐ Near full extension

☐ 30° Flexion

☐ 60° Flexion

☐ 90° Flexion

☐ Other

If other please specify:

19. Have you trialled the manual method for graft tensioning?

☐ Yes

☐ No
20. Please rate how the following factors influence your decision to use a tensioning device:

<table>
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<tr>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Evaluation of available evidence</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No need for an assistant to apply tension</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Impact of tensioning method on operation time</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The implication of attaching a device to the Tibia</td>
<td></td>
<td></td>
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<tr>
<td>Orthopaedic surgical training</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cost of the method</td>
<td></td>
<td></td>
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<tr>
<td>The accuracy of the tensioning device</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If there are other factors that influence your decision please specify:

PROCEED TO NEXT PAGE
Demographic Information:

Surname:

___________________________________________________________

First name:

____________________________________________________________________________

21. Please specify your primary area of practice:

☐ Metropolitan

☐ Regional

☐ Rural/remote

22. Years of experience as an orthopaedic surgeon.

☐ <5 years

☐ 5-9 years

☐ 10-14 years

☐ 15-19 years

☐ >20 years
23. On average how many ACLRs do you perform annually?

- [ ] < 10
- [ ] 10 - 20
- [ ] 21 - 30
- [ ] 31 - 40
- [ ] 41 – 50
- [ ] > 50

26. On average how long do you follow up your ACLR patients?

- [ ] < 3 months
- [ ] 3 – 5 months
- [ ] 6 – 8 months
- [ ] 9 – 11 months
- [ ] ≥ 12 months or longer
27. In your opinion how common are the following limitations long-term?

<table>
<thead>
<tr>
<th>Factors</th>
<th>Never</th>
<th>Uncommon</th>
<th>Common</th>
<th>Very Common</th>
</tr>
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<tbody>
<tr>
<td>Anterior knee pain</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lack of end of range flexion</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Lack of end of range extension</td>
<td></td>
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</tr>
<tr>
<td>Reduced quadriceps strength</td>
<td></td>
<td></td>
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<tr>
<td>Joint instability</td>
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</tr>
<tr>
<td>Inability to return to previous level of function</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Graft failure</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

If there are any other limitations please specify:

SURVEY COMPLETE – Thank you for your time and thoughts on this topic it is greatly appreciated

201
Appendix J  Consent form for pilot survey

Project Title
Graft tensioning practices in anterior cruciate ligament reconstruction: A Pilot survey of Australian orthopaedic surgeons

Principal Investigator
Garry Kirwan
PhD Candidate
School of Health and Rehabilitation Science
University of Queensland
Email: garry.kirwan@uqconnect.edu.au
Phone: (07) 5552 9316

Associate Investigators
Dr Michael Bourke
Dr Philip Dalton
Professor Lucy Chipchase
Associate Professor Trevor Russell

Declaration by Participant
I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without consequence.

Name of Participant (please print) __________________________
Signature __________________________ Date __________________________

Declaration by Researcher¹
I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Researcher² (please print) __________________________
Signature __________________________ Date __________________________

¹ An appropriately qualified member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.
Appendix K  

Participant information form for pilot study

---

**Participant Information Form – School of Health and Rehabilitation Sciences, University of Queensland**

<table>
<thead>
<tr>
<th>Project Title</th>
<th>Graft tensioning practices in anterior cruciate ligament reconstruction: A pilot survey of Australian orthopaedic surgeons</th>
</tr>
</thead>
</table>
| Principal Investigator | Garry Kirwan  
PhD Candidate  
School of Health and Rehabilitation Science  
University of Queensland  
Email: garry.kirwan@uqconnect.edu.au  
Phone: (07) 5552 9316 |
| Associate Investigators | Dr Michael Bourke  
Dr Philip Dalton  
Professor Lucy Chipchase  
Associate Professor Trevor Russell |

---

**Aims and objectives of the project**

The aim of the pilot study is to seek feedback on the design and content of a survey designed to investigate current practices for tensioning grafts in Australia. The survey is to be distributed nationally to determine clinical approaches and opinions on graft tensioning during anterior cruciate ligament reconstruction (ACLR).

**What does participation involve?**

If you agree to participate in the pilot study you will be asked to complete a survey discussing your preferred surgical method and opinions on graft tensioning during ACLR. The survey will take approximately 5 minutes to complete and all information collected will be confidential. Once you have completed the survey you will be asked to provide feedback on the various elements of the survey. Feedback will be collated and implemented into the survey. Once finalised you will be asked to complete the survey again twice over a 2 week period to ensure internal consistency.

**The expected benefits of the research**

The information collated will be important in ensuring the survey has validity and reliability so information collected can be reported with confidence. The survey will be valuable in determining acceptable clinical practice and informing the profession about the views and opinions regarding graft tension during ACLR. This has the potential to influence clinical practice and impact on the future outcomes for patients undergoing ACLR.
Risk associated with participation

There is no foreseeable risk above that of everyday life. Participation is entirely voluntary and stakeholders will not be coerced into participation in the study. There will be no associated consequences associated with a decision to not participate.

Your confidentiality

All information gained from this study will be handled in a strictly confidential manner. It will only be disclosed with your permission, except as required by Law. For the purposes of this study all information collected will be de-identified. Access to this data is restricted to the named investigators. The results of this study will be published in a scientific journal and presented at scientific meetings with all information presented as group data and in no way identifiable.

Participation is voluntary

Participation in this project is voluntary. If you agree to take part in this study but change your mind later, you are free to withdraw consent for your participation at any time, without comment or penalty.

Research contact person

Garry Kirwan
PhD Candidate
School of Health and Rehabilitation Sciences
University of Queensland
Email: garry.kirwan@uqconnect.edu.au
Phone: (07) 5552 9316

The ethical conduct of this research

This study has been cleared in accordance with the ethical review guidelines and processes of the University of Queensland. These guidelines are endorsed by the University's principal human ethics committee, the Human Experimentation Ethical Review Committee and complies with the National Statement on Ethical Conduct in Human Research. You are free to discuss your participation in this study with project staff (contactable on (07)5552 9316). If you would like to speak to an officer of the University not involved in the study, you may contact the School Ethics Officer on 3365 3924.
Appendix L    National survey feedback form

General Information regarding survey feedback

As part of piloting this survey we would value your thoughts and opinions on the structure, content and usability of the survey. When answering the following questions please provide any feedback on ways to improve the survey content.

Overall opinion of the survey

1. How long did the survey take to complete?
   - □ < 2 minutes
   - □ 2 – 4 minutes
   - □ 5 – 7 minutes
   - □ 8 – 10 minutes
   - □ > 10 minutes
2. **OVERALL** how would you rate the following aspects of the survey?

<table>
<thead>
<tr>
<th></th>
<th>Poor</th>
<th>Fair</th>
<th>Good</th>
<th>Excellent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ease of completion</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clarity of questions</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Appropriateness of language</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Survey flow</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3. Do you have any suggestions to improve any of the above aspect?

EASE:

CLARITY:

LANGUAGE:

FLOW:

4. Did you feel any questions could be interpreted in different way?

☐ Yes  Go to Q5

☐ No   Go to Q6

5. Please state which question(s) and outline why it could be interpreted differently
6. Did you feel any questions were irrelevant?

☐ Yes  Go to Q7

☐ No  Go to Q8

7. Please state which question(s) and outline why they were irrelevant

8. Did you feel any questions were misleading?

☐ Yes  Go to Q9

☐ No  Go to Q10

9. Please state which question(s) and outline why they were misleading

10. Were all relevant response options provided in each question

☐ Yes  Go to Q12

☐ No  Go to Q11

11. Please state which question(s) did not provide adequate responses and what needs to be included

12. Would you include any additional questions that would be relevant to determining current tensioning practices
General Information regarding survey

All questions relate to your STANDARD approach to anterior cruciate ligament reconstruction (ACLR). We acknowledge that factors change based on a number of clinical presentations but we are interested in your standard approach assuming ideal conditions.

Graft tension for the purpose of this survey refers specifically to the process where tension is applied to the graft prior to tibial fixation. It DOES NOT relate to the process where tension is applied during pre-conditioning and preparation of the graft.

Completion of the survey implies consent

Overall opinion on graft tensioning

1. In your general opinion how important is the amount of graft tension in relation to achieving the following outcomes:

<table>
<thead>
<tr>
<th></th>
<th>Not Important</th>
<th>Somewhat Important</th>
<th>Very Important</th>
</tr>
</thead>
<tbody>
<tr>
<td>Restoring anterior - posterior knee stability</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>Long term functional outcome</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
</tbody>
</table>

PROCEED TO Q2
Surgical Technique

2. What is your standard graft choice for ACLR?

☐ Semitendinosus Gracilis Autograft

☐ Semitendinosus Gracilis Allograft

☐ Bone Patella Tendon Bone Autograft

☐ Bone Patella Tendon Bone Allograft

☐ Synthetic

☐ Other

If other please describe:

3. Which of the following categories best describes your standard method of tensioning during ACLR?

☐ Manual hand pull Go to Q4

☐ Tensioning device Go to Q13
Manual Tensioning Method

The following questions explore how you approach the manual method and your opinion on the benefits of this approach

4. Which of the following descriptions of a manual method best describes how you apply tension during ACLR?
   - Sustained maximum one-handed pull
   - Sub maximal one-handed pull
   - Other

   If other please specify:

5. Do you aim for a standard amount of tension for all patients?
   - Yes Go to Q6
   - No Go to Q9

6. In your opinion, are you able to estimate the amount of tension applied?
   - Yes Go to Q7
   - No Go to Q8
7. How much tension would you estimate is produced manually to the whole graft?

- < 20N (<5lb)
- 20N – 40N (5 – 8lb)
- 41N – 60N (9 – 13lb)
- 61N – 80N (14 – 17lb)
- 81N – 100N (18 – 22lb)
- > 100N (>22lb)

GO TO Q10

8. How do you standardise the amount of tension?

GO TO Q10

9. What factors influence the amount of tension you apply for each person? (You may select more than one)

- Graft diameter
- Patient anthropometry
- Viscoelastic properties of the graft
- Stability of the knee
- Other

If other please specify:

PROCEED TO Q10
10. At what knee angle do you apply graft tension prior to fixation?

☐ Full hyperextension

☐ Near full extension (0-15 degrees)

☐ 30° Flexion

☐ 60° Flexion

☐ 90° Flexion

☐ Other

If other please specify:

11. Have you ever trialled the use of a tensioning device?

☐ Yes

☐ No
12. Please rate how the following factors influence your decision to select a manual method:

<table>
<thead>
<tr>
<th>Factors</th>
<th>No Influence</th>
<th>Some Influence</th>
<th>Strong Influence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient outcomes achieved with this method</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Evaluation of available evidence</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The need for an assistant to apply tension</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Impact of tensioning method on operation time</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The implication of attaching a device to the Tibia</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Orthopaedic surgical training</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cost of method</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sensory feedback from manual pull</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If there are other factors that influence your decision please specify:

**GO TO Q22 TOP OF PAGE 11**
Tensioning Device Method

The following question are exploring the technique you use for tensioning with a device and your opinion on the benefits of this approach

13. What device do you prefer to use for tensioning?

14. Do you apply a standard amount of tension each time?

☐ Yes Go to Q15

☐ No Go to Q16

15. How much tension do you apply to the graft? (Only select the option which applies to your standard approach. Please indicate units of force, N/lbs)

   a. Semitendinosus strand_____________________

   b. Gracilis strand____________________________

   c. Posterolateral bundle_____________________

   d. Anteromedial bundle______________________

   e. Whole graft________________________________

   GO TO Q19
16. Which factors influence the amount of tension you apply for each person? (You may select more than one)

☐ Graft diameter

☐ Patient anthropometry

☐ Viscoelastic properties of the graft

☐ Stability of the knee

☐ Other

If other please specify:

17. Please state the minimum amount of tension you would apply based on the factors identified in the previous question (Only answer the option(s) that applies to your standard approach and indicate force in newtons or pounds)

a. Semitendinosus strand: ________________________________

b. Gracilis strand: ________________________________

c. Posterolateral bundle: ________________________________

d. Anteromedial bundle: ________________________________

e. Whole graft: ________________________________
18. Please state the maximum amount of tension you would apply based on the factors identified in the previous question (Only answer the option(s) that applies to your standard approach and indicate force in newtons or pounds)

   a. Semitendinosus strand: __________________________
   b. Gracilis strand: __________________________
   c. Posterolateral bundle: __________________________
   d. Anteromedial bundle: __________________________
   e. Whole graft: __________________________

PROCEDURE TO Q19

19. At what knee angle do you apply graft tension prior to fixation?

   ☐ Full hyperextension
   ☐ Near full extension (0-15 degrees)
   ☐ 30° Flexion
   ☐ 60° Flexion
   ☐ 90° Flexion
   ☐ Other

   If other please specify:

20. Have you trialled the manual method for graft tensioning?

   ☐ Yes
   ☐ No
21. Please rate how the following factors influence your decision to use a tensioning device:

<table>
<thead>
<tr>
<th>Factors</th>
<th>No Influence</th>
<th>Some Influence</th>
<th>Strong Influence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient outcomes achieved with this method</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Evaluation of available evidence</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No need for an assistant to apply tension</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Impact of tensioning method on operation time</td>
<td></td>
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</tr>
<tr>
<td>The implication of attaching a device to the Tibia</td>
<td></td>
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<tr>
<td>Orthopaedic surgical training</td>
<td></td>
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<tr>
<td>Cost of the method</td>
<td></td>
<td></td>
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<tr>
<td>The accuracy of the tensioning device</td>
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</tr>
</tbody>
</table>

If there are other factors that influence your decision please specify:

PROCEED TO NEXT PAGE
Demographic Information:

22. Please specify your primary area of practice:
   - [ ] Metropolitan
   - [ ] Regional
   - [ ] Rural/remote

23. Years of experience as an orthopaedic surgeon.
   - [ ] <5 years
   - [ ] 5-9 years
   - [ ] 10-14 years
   - [ ] 15-19 years
   - [ ] >20 years

24. On average how many ACLRs do you perform annually?
   - [ ] < 10
   - [ ] 10 - 20
   - [ ] 21 - 30
   - [ ] 31 - 40
   - [ ] 41 – 50
   - [ ] > 50
25. On average how long do you follow up your ACLR patients?

☐ < 3 months

☐ 3 – 5 months

☐ 6 – 8 months

☐ 9 – 11 months

☐ ≥ 12 months or longer
26. In your opinion how common are the following limitations long-term?

<table>
<thead>
<tr>
<th>Factors</th>
<th>Never</th>
<th>Uncommon</th>
<th>Common</th>
<th>Very Common</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anterior knee pain</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>General knee pain</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lack of end of range flexion</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lack of end of range extension</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Reduced quadriceps strength</td>
<td></td>
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<tr>
<td>Reduced hamstring strength</td>
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<tr>
<td>Joint instability</td>
<td></td>
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<tr>
<td>Inability to return to previous level of function</td>
<td></td>
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<td></td>
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<tr>
<td>Graft failure</td>
<td></td>
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</tr>
</tbody>
</table>

If there are any other limitations please specify:
Surgeon Name:

This information is only being collected to identify eligible participants to win the Mont Blanc pen being offered in appreciation for your time. Name will be collected independently and not linked to the responses submitted. Providing this information is optional

Surname:

______________________________________________________________________________

First name:

______________________________________________________________________________

SURVEY COMPLETE - Thank you for your time and thoughts on this topic it is greatly appreciated
Appendix N  Letter to the Editor and Author’s Reply

Letter to the editor

The following article was submitted in response to study one


Author’s reply


We would like to acknowledge the important contribution from Dr Sorel and colleagues on this topic and thank them for their interest in our review. As discussed by Sorel et al (2014), the correlation between graft size, graft tension and patient outcomes has yet to be established in the literature (Sorel et al., 2014). Indeed, the effect of either graft size or graft tension has received little attention. Our review focused specifically on graft tension and highlighted the lack consensus regarding optimal tension. The little work that has examined the effect of graft size on patient outcomes has conflicting results. For example, Mariscalco et al (2013) reported that a reduction in graft cross sectional area resulted in poorer outcome on the Knee injury and Osteoarthritis Outcome Score (Mariscalco et al., 2013) while Kamien et al (2013) reported that graft size did not impact on outcomes based on the Tegner score and failure rate post ACLR (Kamien et al., 2013). However, neither of these studies discussed tension much like the studies on tensioning fail to discuss graft size.
Based on a theoretical model as proposed by Sorel et al (2014), we agree that graft size and tension are likely to be correlated (Sorel et al., 2014). Based on the currently available clinical evidence, it is reasonable to conclude that 78.5N to 90N may result in less STSD in anterior stability. It is vital, however, that further research is conducted in this field to elucidate the relationship between graft size and tension and how this impacts on outcomes post ACLR. We believe our review has taken the first step to establish an argument for optimal tension although further work on how this tension is achieved and the relationship to graft size is required.