**Initial graft tension and the effect on post-operative patient functional outcomes in
anterior cruciate ligament reconstruction: A Systematic review**

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No benefits or funds were received in support of the study.

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Short Running Title: Tension and Function post ACL Reconstruction

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 randomized trials with a NHMRC level of evidence of III or higher published between 1950 and July 2012. Articles utilizing a semitendinosis-gracilis or bone patella-tendon bone autograft that reported graft tension and post surgical 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 trend towards an initial graft tension of 78.5N-90N resulting in a reduced STSD in anterior laxity as measure by an instrumented knee laxity device. However,

there is insufficient evidence to conclude if patient-specific function is improved at any specific tension.

Level of Evidence: Level II systematic review

Clinical Relevance: This systematic review of randomized 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.

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)(1-4). 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 (4-7). 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(5, 8). As a result many surgeons rely on achieving an observed isometric graft prior to fixation to guide the amount of tension applied(9).

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(10-12). In recent years, attempts have been made to quantify graft tension with the introduction of tensioning devices(7, 13-15). 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(8, 16, 17). 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), $p=0.002$)(2). 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(5, 8). In human studies a recent qualitative review of

randomized controlled trials suggested 80N of tension in a semitendinosis-gracilis graft produces less side-to-side difference (STSD) in anterior tibial displacement(5). 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(5).

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.

Methods

A protocol outlining the search strategy, inclusion and exclusion criteria, quality assessment and data extraction was developed according to existing standards for systematic reviews(18, 19). 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, 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).

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 semitendinosis-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(20). A sample of articles reviewed for inclusion were assessed by a second author to ensure reliability (GK). A third reviewer was available to arbitrate if consensus was not reached.

Articles were critically appraised (MB and PD) using a quality appraisal tool adapted from Bourke et al. (2010)(21, 22) and each article was given a score out of 12 based on the criteria presented in Table 1. All Included articles were ranked according to the NHMRC levels of evidence scale (I-IV)(20)

Table 1: Methodology Quality Assessment Score

Methodology Criteria*
1. Was there clear concealment of allocation?
2. Were the inclusion and exclusion criteria clearly defined?

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

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

A data extraction tool was developed for the purpose of this review based on the PRISMA guidelines(19) 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 2.

Table 2: Characteristics of Included Studies

Randomized Studies	Patient Demographics			Study Characteristics			Arthrometer Measurement (mm)			Other Outcome Measures		
	Sample Size	M:F	Age	Graft Choice	Tension Applied (N)	Angle at Fixation (degrees)	Pre-op STSD mm	Post-Op STSD mm	12/24 month STSD mm	IKDC Category	Quadriceps Strength %	Hamstring Strength %
Kim et al (2006)	43	29:19	Gr 1 – 27.1 Gr 2 – 22.6 Gr 3 – 23.7	STG	Gr 1-78.5N Gr 2 - 117.7N Gr 3- 147.1N	30 ⁰	Gr 1 – 5.6 (1.9) Gr 2 – 5.0 (2.0) Gr 3 – 6.3 (2.6)	NR	Gr 1 – 1.3 (1.4) Gr 2 – 2.1 (1.9) Gr 3 – 2.4 (2.2)	NR	Gr 1 – 90.9 (18) Gr 2 – 91.3 (11.7) Gr 3 – 88.8 (8.4)	NR
Nicholas et al (2004)	49	33:16	Gr 1 – 30+/-7 Gr 2 – 33+/-8	BPTB	Gr 1 – 45N Gr 2 – 90N	Full Ext	Gr 1 – 5.3 (2.4) Gr 2 – 5.7 (2.7)	Gr 1 – 2.4 (2.4) Gr 2 – 1.1 (1.7) ^{**}	Gr 1 – 3.0 (2.2) Gr 2 – 2.2 (1.6)	NR	NR	NR
Van Kampen et al (1998)	38	27:11	Gr 1 – 28 Gr 2 - 28	BPTB	Gr 1 – 20N Gr 2 – 40N	20 ⁰	NR	NR	Gr 1 – 2.6 (1.3) Gr 2 – 2.5 (1.8)	Gr 1 Cat A n=2 Cat B n=10 Cat C n=6 Cat D n=1 Gr 2 Cat A n=1 Cat B n=10 Cat C n=8 Cat D n=0	NR	NR
Yasuda et al (1997)	64	38:32	Gr 1 – 22.7+/-6.7 Gr 2 – 23+/-5.7 Gr 3 – 25.5+/-8.1	STG	Gr 1 – 20N Gr 2 – 40N Gr 3 – 80N	30 ⁰	Gr 1 – 5.1 (1.9) Gr 2 – 6.3 (2.1) Gr 3 – 5.9 (1.8)	Gr 1 – 2.2(2.4) Gr 2 – 1.4 (1.8) Gr 3 – 0.6 (1.7) [*]	NR	NR	Gr 1 – 92 Gr 2 – 89 Gr 3 - 91	Gr 1 – 99 Gr 2 – 96 Gr 3 – 99
Yoshiya et al (2002)	43	21:22	Gr 1 – 23 Gr 2 - 23	BPTB	Gr 1 – 25N Gr 2 – 50N	Full Ext	NR	Gr 1 - -2.0 Gr 2 - -1.8	NR	NR	NR	NR

Abbreviations: NR – Not Reported, Gr – Allocated study group, STG – Semitendinosis Gracillis 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(23). 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).

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 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 article not focused on ACLR (n=105) with the remaining being animal and 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.

The methodological score for each study is presented in Table 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: Methodological Quality Assessment Score

Article	Criteria												Total Score	Evidence Level*
	1	2	3	4	5	6	7	8	9	10	11	12		
Kim et al (2006)	0	0	1	0	1	1	0	1	1	0	0	0	5	II
Nicholas et al (2004)	1	0	1	1	1	1	1	1	1	0	0	0	8	II
Van Kampen et al (1998)	0	0	1	0	1	1	0	1	1	0	0	0	5	II
Yasuda et al (1997)	0	0	1	1	1	1	0	1	0	0	0	0	5	II
Yoshiya et al (2002)	0	1	1	0	1	1	0	1	1	0	0	0	6	II

* Based on NHMRC Level of Evidence Guidelines(20)

Study characteristics

Participant numbers ranged from 38 to 64 participants with a bias towards males (approximately 2:1). Participant ages were similar (24.7 ± 3.6 years) as was follow up duration (19.5 ± 5.0 months) across studies (Table 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)(13, 14, 24) with 40N reported in a further two studies(13, 14). 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(7, 13-15, 25). Kim et al (2006), Van Kampen et al (1998) and Yoshiya et al (2002) reported no significant difference between groups immediately post surgery or greater than 12 months post surgery(13, 15, 25). Nicholas et al (2004) reported significantly less STSD in

anterior tibial displacement at 90N of tension when compared to 45N immediately post surgery ($p=0.01$)(7). Yasuda et al (2002) reported 80N of tension resulted in significantly less STSD in anterior tibial displacement when compared to 20N immediately post surgery ($p=0.05$)(14) (Table 2)

Quantitative comparison of STSD in anterior tibial displacement between articles was performed using effect size represented as a standardised mean difference with 95% confidence intervals. 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 2).

There was a reduction in the STSD in anterior tibial displacement from pre to post surgery for all articles(7, 13-15, 25). 80N of initial tension produced the largest effect (Standardised mean difference -2.98; 95% CI -3.82, -2.14)(14) while 45N produced the smallest effect (Standardised mean difference -1.19; 95% CI -1.83, -0.54)(7) (Figure 2). Between pre and ≥ 12 months post surgery the greatest effect was produced at 78.5N (Standardised mean difference -2.45; 95% CI -3.40, -1.51)(25) and again the smallest effect produced at 45N of initial tension (Standardised mean difference -0.98; 95% CI -1.61, -0.35)(7) (Figure 3).

Between-tension comparison at ≤ 2 weeks post surgery demonstrated the largest effect in favor of 80N compared to 20N (Std Mean Difference 0.76; 95% CI 0.17-1.35)(14) and the smallest effect towards 40N compared to 20N (Std Mean Difference 0.37; 95% CI -0.21-0.95) (Figure 4)(14). At ≥ 12 months post surgery, the largest effect was towards 78.5N compared to 147.1N (Std Mean Difference -0.58; 95% CI -1.29-0.13)(25) and the smallest

effect towards 40N compared to 20N (Std Mean Difference 0.06; 95% CI -0.58-0.70)(13) (Figure 5).

Additional outcome measures

The IKDC Subjective Knee Form was collected in two articles(13, 15). 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(13).

Two articles compared knee range of movement between various tenions with both reporting no significant difference in either loss of flexion or extension between groups at 20-24 months post surgery(7, 14). Two articles compared quadriceps and hamstring strength as a percentage of injured and non injured with both articles reporting no significant difference between tensions(14, 25).

Discussion

Graft choice, tunnel placement, initial graft tension and angle of fixation are all thought to contribute to functional outcomes in ACLR(16, 26, 27). This review aimed to evaluate the influence of initial graft tension on such outcomes. Quantative 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(28-32) and the current literature failed to adequately report more appropriate measure.

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 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 significantly better outcome at 80N and 90N respectively(7, 14). 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 (Std mean difference 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(28, 30, 31). 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(28-33). A recent study by Kocher et al (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(31). 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(28). 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 2). Based on the assessment of quality (Table 3) only one article

demonstrated robust methodology sufficient to draw a valid conclusion(7). 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(5). 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.

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