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Lack of consensus regarding pretensioning and preconditioning protocols for soft tissue graft reconstruction of the anterior cruciate ligament

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Abstract
Purpose Pretensioning and preconditioning of soft tissue grafts are often performed to obviate graft stress relaxation and elongation due to viscoelastic graft properties following anterior cruciate ligament (ACL) reconstruction. It was hypothesized that a consensus could be identified in the current literature regarding the biomechanical effects and clinical benefits of an optimal protocol.
Methods A systematic electronic literature search was performed by two independent reviewers to identify relevant publications. Only studies describing and/or comparing pretensioning or preconditioning protocols of soft tissue grafts or equivalent animal research models were eligible for inclusion. Study design, graft type, and protocol, including method, magnitude, mode (cyclic and/or static loading), and duration of load application, were compared. Research results and clinical conclusions were also evaluated for each study.
Results Five studies, including four in vitro biomechanical investigations and one histological analysis of patient tissue, met the predefined criteria for inclusion. Studies described numerous pretensioning and/or preconditioning protocols with varying force, time, and application modalities for multiple soft tissue graft types and animal models. The majority of studies (80 %) utilized at least one pretensioning or preconditioning protocol between 80 and 89 N, while only one study investigated substantially higher loads (500 N).
Conclusions Despite common trends demonstrating the effects of pretensioning and preconditioning, no clear consensus regarding an optimal protocol, magnitude, or modality could be identified within the currently available relevant literature. Further multidisciplinary research is required before an optimal or consensus protocol can be established for soft tissue ACL reconstruction. Regardless, the current biomechanical literature demonstrates the potential clinically beneficial effects of pretensioning and preconditioning, including reduced graft elongation and greater preservation of graft tension and stiffness following fixation.
Level of evidence Systematic review, Level II.

Keywords Soft tissue grafts · Hamstring graft · Preconditioning · Pretensioning · Anterior cruciate ligament reconstruction · Systematic review

Introduction

Clinical outcomes following anterior cruciate ligament (ACL) reconstructions are influenced by multiple variables including graft selection, biology, biomechanical properties, reconstruction technique, tunnel placement, initial graft tension, fixation method, and post-operative rehabilitation [1, 7–9, 12, 14, 16, 18, 21, 24, 26]. Additional intrinsic factors of soft tissue grafts, including viscoelastic properties, can lead to stress relaxation and graft elongation post-operatively and result in continued knee laxity [2, 4, 5, 10, 19, 23, 25–27]. Pretensioning and preconditioning protocols are often implemented prior to final fixation to obviate post-operative viscoelastic graft elongation [2, 4, 5, 19].

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The use of soft tissue grafts, particularly hamstrings, for ACL reconstruction has increased in recent years [7, 8, 12, 20, 22] and has been reported to be the preferred graft in the majority of ACL reconstructions performed globally [17, 22]. Despite increasing popularity, significant uncertainty exists regarding pretensioning and/or preconditioning protocols for soft tissue ACL reconstruction [3, 6]. Current time zero biomechanical research suggests pretensioning and preconditioning protocols impart improved time zero graft characteristics including reduced graft elongation following fixation and greater post-operative preservation of graft tension and stiffness [4, 6, 15, 19]. However, the biomechanical basis of current clinical protocols and loads is unclear. Therefore, the purpose of this review was to systematically survey the current literature and determine whether an optimal pretensioning and/or preconditioning protocol or methodological consensus exists. It was hypothesized that a consensus could be identified in the current literature regarding an optimal protocol in addition to its biomechanical effects and clinical benefits. Furthermore, this review also sought to identify current knowledge gaps and guide necessary areas of future research.

Materials and methods

This systematic review was conducted according to the guidelines outlined by the Cochrane Handbook [13].

Criteria for inclusion in this review

Types of studies

In vivo and in vitro studies describing and/or comparing soft tissue pretensioning or preconditioning protocols were eligible for inclusion.

Types of specimens

Studies that utilized human soft tissue grafts or appropriate animal models were eligible for inclusion. Studies describing pretensioning or preconditioning protocols for grafts not exclusively composed of soft tissue, e.g. bone–patellar tendon–bone (BTB), were not included in the analysis.

Types of interventions

Duplicates in the database search query results were manually removed. Only studies available in English were eligible for inclusion. Studies without implications for ACL reconstruction were also excluded as the primary focus of the review was to identify pretensioning and preconditioning protocols utilized for soft tissue ACL reconstruction.

Types of outcome measures

Data were compiled using a spreadsheet (Microsoft Corp, Redmond, WA, USA). Demographic data, including authors, year of publication, and publishing journal, were recorded. Study data including study design, graft type, pretensioning/preconditioning load, time, mode of application, quantitative comparative metrics, and study conclusions were extracted and reported. Additional relevant descriptive data were extracted based on the individual study design. Data were deemed relevant by consensus between reviewers. Commonly reported measurements and extracted variables included graft elongation (creep) removed during pretensioning or preconditioning (mm), graft tension at specific time points after fixation (N), graft stiffness (N/mm), ultimate failure strength (N), changes in collagen fibrillar ultrastructure (cohesion, integrity, and parallelism) after pretensioning, and graft elongation during cyclic loading (mm).

Search strategy

A systematic electronic search was performed using the MEDLINE, EMBASE, and Cochrane databases by two independent reviewers (KAJ and BTW). The systematic search was performed in July, 2014. The following key search terms were used in all fields: “soft tissue” AND “preconditioning”, “soft tissue” AND “precondition”, “soft tissue” AND “pretensioning”, “soft tissue” AND “pretension”, “hamstring” AND “preconditioning”, “hamstring” AND “precondition”, “hamstring” AND “pretensioning”, and “hamstring” AND “pretension”. Select orthopaedic and sports medicine journals were also independently searched from July 2013 to July 2014 to identify any studies that may not yet be searchable through the queried databases including *The American Journal of Sports Medicine, Archives of Orthopaedic and Trauma Surgery*, *Arthroscopy: The Journal of Arthrocopic and Related Research*, *The Bone and Joint Journal, Clinical Orthopaedics and Related Research*, *The Journal of Bone and Joint Surgery*, *Journal of Orthopaedic Research*, and *Knee Surgery Sports Traumatology Arthroscopy*. Following the identification of articles for inclusion from the primary search queries, the bibliographies of the included studies were manually reviewed for any additional relevant literature describing and/or comparing soft tissue graft pretensioning or preconditioning protocols.

Data collection and analysis

Selection of studies

Following removal of duplicates (173) and non-English articles (35), results were screened by title and abstract by

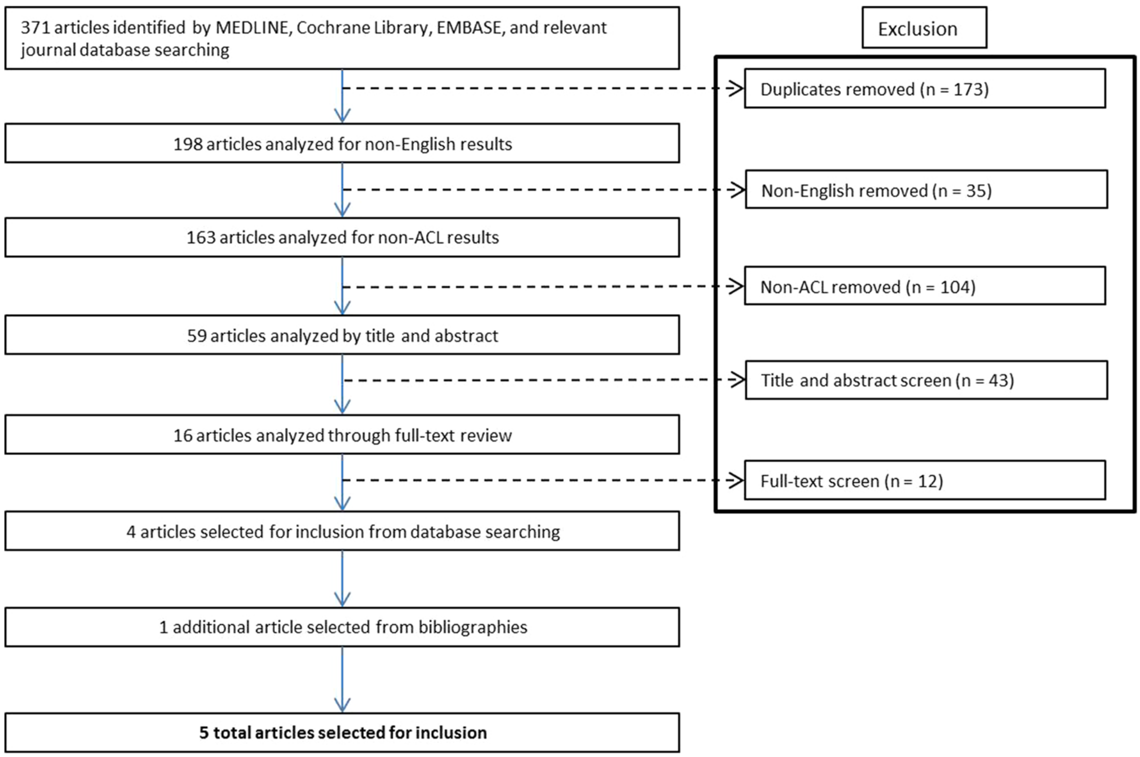

Fig. 1 Diagram illustrating the decision factors and quantifying the selection, inclusion, and exclusion of studies for review

two independent reviewers. Articles pertaining to, describing, and/or comparing soft tissue graft pretensioning and/or preconditioning protocols relevant to ACL reconstruction based on information available in the title and abstract were selected for full-text review (Fig. 1). If the title and abstract review was in anyway inconclusive, then full-text review was performed. Disagreements between reviewers concerning inclusion eligibility were resolved by consensus.

Data extraction and management

Data describing pretensioning and preconditioning techniques were extracted using predefined and standardized spreadsheets. For such purposes, pretensioning was defined as graft loading prior to implantation, while preconditioning referred to intra-articular graft loading (or simulated equivalents) following fixation at one end [19]. For consistency and comparison, these designations were applied independent of the nomenclature used in individual studies. Both reviewers independently extracted data with any discrepancies resolved by consensus.

Results

Database queries yielded a total of 371 articles [MEDLINE (99), Cochrane Libraries (6), EMBASE (123), and other orthopaedic journals (143)] (Fig. 1). After removing duplicates (173), non-English articles (35), and articles without ACL reconstruction implications (104), 59 studies remained. Title and abstract screening removed 43 studies and identified 16 studies for full-text review. Both reviewers independently selected the same four studies for inclusion [4, 11, 15, 19]. Independent bibliographic review of the four included studies identified one additional article [6] for a final total of five. Included studies were published between 2004 and 2012, had a different first author, and were published in four orthopaedic journals including *The American Journal of Sports Medicine* [4, 19], *Arthroscopy: The Journal of Arthrocopic and Related Research* [15], *The Knee* [6], and *Knee Surgery Sports Traumatology Arthroscopy* [11].

Study design

Human tissue grafts, including anterior tibialis, quadruple-strand semitendinosus/gracilis, and 4-strand semitendinosus, were utilized in the majority of studies (3/5, 60 %) [4, 11, 19]. The two remaining studies utilized porcine models for biomechanical testing [6, 15]. In vitro biomechanical investigations were the most common (4/5, 80 %) [4, 6, 15, 19]. Only one study utilized human patient tissue, which was only analysed histologically [11]. No in vivo investigations, clinical trials, or patient outcomes studies were described in the articles meeting the inclusion criteria.

Pretensioning and preconditioning protocols

Complete study descriptions of pretensioning and preconditioning protocols are displayed in Table 1. Pretensioning protocols were generally longer, ranging in duration from 15 min [4, 15, 19] to 30 s [11]. Standardized instrumented preconditioning methods were typically shorter and ranged in duration from 5 min [15] to 100 s [19] for static protocols, while all described cyclic protocols utilized 25 cycles over a period of 100 s (0.25 Hz) [4, 19].

For pretensioning techniques, applied forces ranged from 80 N to 500 N; however, the majority of studies (4/5, 80 %) described at least one pretensioning load within the relatively narrow range of 80–89 N [4, 6, 15, 19]. Among studies describing an instrumented preconditioning protocol, both cyclic and static modalities utilized a maximum applied force between 80 N and 89 N [4, 15, 19].

Efficacy of pretensioning and preconditioning protocols were assessed via quantitative comparisons of changes in graft length (elongation), displacement, graft ultimate failure load, stiffness, and graft tension [4, 6, 15, 19] (Table 2). Histological analysis was only reported in a single study [11].

Discussion

The most important finding of this systematic review was the identification of commonalities among pretensioning and preconditioning protocols, including a limited range of magnitude and duration of applied forces. However, given the combination of the limited number of studies and the variability of design and reported results, neither a consensus nor optimal protocol could be confidently identified from the information available in the current literature.

Four of the five included studies presented some data demonstrating the beneficial biomechanical effects of pretensioning and/or preconditioning. Elias et al. [4] demonstrated that an increased load during pretensioning (160 N vs. 80 N) reduced, but did not completely eliminate the subsequent loss of graft tension and stiffness following final graft fixation. Lee et al. [15] reported that intra-articular static preconditioning resulted in a significant reduction in graft elongation during cyclic loading compared with a maximal manual preconditioning both with and without static pretensioning. Figueroa et al. [6] reported that pretensioning removed graft elongation (3 %) relative to non-pretensioned controls; however, ultimate load-to-failure of pretensioned grafts was significantly lower. Finally, Nurmi et al. [19] reported higher initial tensions following interference screw insertion for both static and cyclically preconditioned grafts compared with unconditioned controls. However, only cyclically preconditioned grafts demonstrated significantly higher graft tension after 10 min.

Collectively, the findings of the included studies indicate future research is required to more conclusively determine optimal pretensioning and preconditioning protocols to be used for ACL reconstruction. Despite common literature trends, including magnitude, mode, and duration of applied forces, there is insufficient data to draw meaningful conclusions regarding consensus or biomechanically and clinically optimal protocols. Data from Elias et al. [4] and Nurmi et al. [19] suggest that higher load protocols have not been sufficiently investigated and optimized given that significant graft stress relaxation was observed following "clinically practical" loading protocols and ranges described in the majority of included studies [4, 6, 15, 19]. Specifically, Nurmi et al. [19] reported that 60 % of the initial graft tension may be lost in the first hour when grafts are pretensioned using "clinically practical" protocols (15 min @ 88 N). Elias et al. [4] suggests that higher loads may be beneficial; however, Figueroa et al. [6] and Guillard et al. [11] have questioned the adverse effects of pretensioning loads on ultimate failure strength and collagen ultrastructure, respectively. Based on the available literature, it would seem that several questions have yet to be sufficiently investigated and answered.

Furthermore, all articles meeting the criteria for inclusion involved time zero analysis. Consequently, the long-term clinical results and patient outcomes following such protocols are largely unknown. With only five studies found through database searching and bibliographic review, it is clear that additional interdisciplinary research and quantitative comparisons of different pretensioning and preconditioning protocols, particularly using higher applied loads, are required. Results from Guillard et al. [11] suggest that substantially higher pretensioning loads (500 N) could potentially be used; however, such loads must be applied transiently (less than 30 s) to minimize destructive changes to collagen ultrastructure. Yet, the effects of such loads on graft biomechanical properties (stiffness, stress relaxation, ultimate failure, etc.) are not sufficiently investigated within the current literature. The authors believe that additional investigations are required to identify an optimal pretensioning and/or preconditioning protocol (load, duration, etc.) to impart ideal biomechanical graft properties at time zero without negatively impacting graft biomechanical or histological properties over the long term. Ultimately, randomized controlled trials evaluating patient outcomes following various soft tissue graft pretensioning or preconditioning protocols will be required to evaluate the clinical efficacy. Nonetheless, based on currently available biomechanical research, the authors believe that the surgical implementation of pretensioning and preconditioning protocols is necessary to obviate some of the potential viscoelastic consequences of soft tissue graft reconstruction during the post-operative period including graft elongation and loss of both graft tension and stiffness.

Table 1 Summary of experimental details including graft type and quantity and pretensioning and preconditioning protocols

References	Graft type/number	Pretensioning protocol			Preconditioning protocol			
		Load	Time	Additional Notes	Load	Time	Modality	Additional Notes
Elias et al. [4]	Quadruple-strand semitendinosus/gracilis ($n = 6$)	80 N	15 min	Specimens tested once using each protocol, randomized testing order	0–80 N	100 s	Cyclic (25 cycles)	Cycled in displacement control to the displacement initially achieved under 80 N of tension. Uniform across testing groups. Graft unloaded for 1 min prior to preconditioning
		160 N	15 min		0–80 N	100 s	Cyclic (25 cycles)	
Figueroa et al. [6]	Porcine extensor tendon ($n = 50$, 25 per group)	No pretensioning		Pretensioning performed on commercially available graft preparation/tensioning board	–	–	–	–
		80 N	10 min		–	–	–	–
Guillard et al. [11]	4-strand semitendinosus ($n = 38$ patients, 8, 13, and 17 per group, respectively)	500 N	30 s	Grafts consisted of autograft 4-strand semitendinosus and a polyethylene terephthalate (PET) strip hybrid transplant	–	–	–	–
		500 N	2 min		–	–	–	–
		500 N	5 min		–	–	–	–
Lee et al. [15]	Porcine profundus flexor digital tendons ($n = 27$, 9 per group)	–	–	–	Maximum manual pull (45–65 N)	30–50 s	Manual pull (static)	–
		89 N	15 min	Pretensioning performed on commercially available graft preparation/tensioning board	Maximum manual pull (45–65 N)	30–50 s	Manual pull (static)	–
		–	–	–	89 N	5 min	Static	–
Nurmi et al. [19]	Anterior tibialis tendons ($n = 42$, 14 per group)	88 N	15 min	Uniform across three testing groups. Pretensioning performed on commercially available graft preparation/tensioning board	No preconditioning	–	–	–
					0–80 N	100 s	Cyclic (25 cycles)	–
					80 N	100 s	Static	–
	Anterior tibialis tendons ($n = 10$)	88 N	15 min	Pretensioning performed on commercially available graft preparation/tensioning board	80 N	100 s	Static	–
	Quadruple-strand semitendinosus/gracilis ($n = 10$)	88 N	15 min		80 N	100 s	Static	–

Table 2 Summary of experimental methods following pretensioning/preconditioning and corresponding results and conclusions

References	Pretensioning/preconditioning	Methods	Results	Conclusions
Elias et al. [4]	80/0–80 N (25 cycles)	Grafts were tensioned to 80 N to represent application of initial tension during ACL reconstruction and held at a fixed displacement. Tension and stiffness were measured at 5 min and 3 h	40 ± 3 N (tension) and 152 ± 17 N/mm (stiffness @ 5 min), 21 ± 4 N and 124 ± 17 N/mm (@ 3 h)	Increased tension (160 vs. 80 N) during preconditioning can significantly reduce postoperative loss of tension and stiffness due to viscoelasticity
	160/0–80 N (25 cycles)		50 ± 6 N and 173 ± 16 N/mm (@ 5 min), 30 ± 7 N and 146 ± 21 N/mm (@ 3 h)	
Figueroa et al. [6]	No pretensioning/no preconditioning	Graft elongation was measured after pretensioning. Progressive and continuous tension was applied until ultimate failure	No elongation (control), 229.9 ± 65.26 N ultimate failure	Pretensioning (80 N) can reduce graft elongation after fixation; however, it has the potential to significantly reduce ultimate failure strengths
	80 N/no preconditioning		3% graft elongation, 189.7 ± 60.73 N ultimate failure	
Guillard et al. [11]	500 N/no preconditioning	Samples from the mid-portion of grafts were taken before and after pretensioning. Scanning electron microscopy (SEM) was used to provide a semi-quantitative assessment of collagen cohesion, integrity, and parallelism	Significant loss of collagen parallelism, cohesion, and fibril integrity was observed after pretensioning. More significant disorganization, specifically loss of cohesion, was observed for 2 and 5 min pretensioning times compared to 30 s	High-load pretensioning (500 N) of ACL grafts results in detectable alterations in collagen fibrillar ultrastructure when applied for extended durations
Lee et al. [15]	No pretensioning/maximum manual pull (45–65 N)	After pretensioning/preconditioning, grafts were cyclically loaded from 0 to 150 N @ 1 Hz for 1000 cycles. Grafts were then pulled to failure at a rate of 150 mm/min. Elongation, ultimate failure, and stiffness were recorded. Nine intact porcine ACL were tested for the purpose of comparison	12.5 ± 1.1 mm (elongation), 718.5 ± 141.0 N (ultimate failure), 32.5 ± 9.7 N/mm (stiffness)	Static intra-articular preconditioning resulted in significantly less cyclic displacement at time zero. Both pretensioning and preconditioning resulted in significantly stiffer grafts. All grafts were significantly different (↑ elongation, ↓ ultimate failure, ↓ stiffness) compared to the native porcine ACL (results not shown herein)
	89 N/maximum manual pull (45–65 N)		8.8 ± 0.8 mm, 778.6 ± 227.0 N, 53.1 ± 9.1 N/mm	
	No pretensioning/89 N		5.4 ± 0.3 mm, 777.1 ± 255.0 N, 47.9 ± 17.6 N/mm	
Nurmi et al. [19]	88 N/no preconditioning	An initial tension of 80 N was applied to grafts, and a bioabsorbable interference screw was inserted for fixation. Graft tension was recorded immediately after fixation and after 10 min	79 ± 19 N (tension after screw insertion), 49 ± 16 N (tension @ 10 min)	Preconditioning (80 N static, 0–80 N cyclic) resulted in a significant increase in initial tension; however, significant graft tension was lost over the next 10 min
	88/0–80 N (25 cycles)		100 ± 17 N, 60 ± 11 N	
	88/80 N		102 ± 15 N, 64 ± 12 N	
	88/80 N (Anterior tibialis)	Grafts were clamped (no interference screw) and initially tensioned to 80 N. Residual tension was recorded at 1, 10, and 60 min	67 ± 2.5 N (tension @ 1 min), 45 ± 2.2 N (@ 10 min), 29 ± 2.8 N (@ 60 min)	Approximately 60 % of initial graft tension can be lost within 60 min of fixation. "Clinically applicable" pretensioning/preconditioning protocols (88/80 N) cannot eliminate intrinsic viscoelasticity of soft tissue ACL grafts
	88/80 N (Semitendinosus/gracilis)		67 ± 2.0 N, 46 ± 4.1 N, 34 ± 4.9 N	

The authors acknowledge the limitations of the present review. Foremost, the present study excluded non-English articles. Reviewing non-English articles may have contributed additional relevant information; however, due to time and the required translation, these articles could not be included. Furthermore, the identification of all relevant articles, accidental removal of any relevant papers during abstract and full-text review, or errors in data extraction is a concern. However, both of the reviewers independently queried a comprehensive set of databases and individual journals, identified articles for inclusion, and extracted all data from relevant studies. Therefore, the authors are confident both in the articles included and the extracted data presented in this review.

Conclusions

Given the limited number of studies and variable results, neither an optimal nor consensus pretensioning or preconditioning protocol for soft tissue ACL reconstruction was established from the current relevant literature. Future multidisciplinary research is required and should focus on quantifying and comparing different (higher load) pretensioning and preconditioning protocols using biomechanical, histological, and clinical metrics to optimize the time zero and long-term properties of soft tissue grafts used for ACL reconstruction. Nevertheless, common trends demonstrating the potential clinically beneficial effects of pretensioning and preconditioning at time zero were observed, including reduced graft elongation following fixation and improved preservation of graft tension and stiffness in the immediate post-operative period.

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