Functional anterior cruciate ligament braces may have a role in select patient groups although there is presently limited evidence supporting or refuting their routine use: A scoping review of clinical practice guidelines and an updated bracing classification

Andrew G. Geeslin | Gilbert Moatshe | Lars Engebretsen | Martin Lind | Frida Hansson | Anders Stalman | Bjorn Barenius | Robert F. LaPrade

1Department of Orthopedics and Rehabilitation, University of Vermont Larner College of Medicine, Burlington, Vermont, USA
2Department of Orthopedic, University of Oslo, Oslo, Norway
3Orthopedic Surgery, Aarhus University Hospital, Århus N, Denmark
4Stockholm Sports Trauma Research Center, FIFA Medical Center of Excellence, MMK, Karolinska Institutet, Capio Arto Clinic, Stockholm, Sweden
5Twin Cities Orthopedics, Edina, Minnesota, USA

Correspondence
Andrew G. Geeslin, Department of Orthopaedics and Rehabilitation, University of Vermont Larner College of Medicine, 95 Carrigan Dr, Stafford Hall, 4th Floor, Burlington, VT 05405, USA.
Email: andrewgeeslinmd@gmail.com

Abstract
Purpose: The purpose of this study was to perform a scoping review of clinical practice guidelines (CPGs) concerning the use of functional anterior cruciate ligament (ACL) braces and to clarify the nomenclature for bracing relevant to ACL injury treatment in order to support prescribing clinicians.

Methods: A PubMed search for CPGs for the use of braces following ACL injury or reconstruction was performed. CPGs on the treatment of ACL injuries with sufficient attention to postoperative braces were included in this scoping review. The references used for supporting the specific CPG recommendations were reviewed. Specific indications for brace use including brace type, period of use following surgery and activities requiring brace use were collected.

Results: Six CPGs were identified and included this this review. Three randomised trials provided the evidence for recommendations on functional brace use following ACL reconstruction in the six CPGs. Functional ACL braces were the primary focus of the three randomised trials, although extension braces (postoperative knee immobilisers) were also discussed. A novel dynamic ACL brace category has been described, although included CPGs did not provide guidance on this brace type.

Conclusions: Guidance on the use of functional ACL braces following ACL reconstruction is provided in six CPGs supported by three randomised trials. However, the brace protocols and patient compliance in the randomised trials render these CPGs inadequate for providing guidance on the use of functional ACL braces in the general and high-risk patient populations when returning to sport after ACL reconstruction. Functional ACL braces are commonly utilised during the course of ACL injury treatment although there is presently limited evidence supporting or refuting the routine use of these braces.
INTRODUCTION

Orthopaedic sports medicine research continues to focus on the treatment of anterior cruciate ligament (ACL) tears, and this sustained level of research interest is likely driven by a high rate of ACL reconstruction graft failure, meniscus tears and post-traumatic osteoarthritis. Certain patient groups, most notably adolescents in pivoting sports, are at an elevated risk of graft failure. Additionally, certain factors, including genu recurvatum, generalised laxity, coronal plane malalignment, concomitant collateral ligament injury, meniscal deficiency or untreated meniscal root and ramp tears, use of allografts in younger patients and sagittal plane malalignment (increased posterior tibial slope), increase the risk of graft failure [5, 6, 14, 15, 17, 24, 27, 32].

Biologic factors including the time required for graft maturation and restoration of muscle strength may provide justification for the use of functional ACL braces. The process of maturation of the tendon graft into a ligament-like structure may play a role in both early and late graft failures. Animal studies have demonstrated that the ACL graft does not achieve biomechanical properties after healing that match the native ACL [7, 31]. Additionally, a systematic review by Johnston et al. reported that knee extensor strength is not restored before 24 months following ACL reconstruction, although this varies depending on autograft selection [12]. These factors may play a role in early graft failures due to elongation and low energy reinnjury and graft failures upon return to sport. Decisions on the use of bracing during the treatment of these injuries are complicated by inconsistent nomenclature and variable treatment protocols. Although indications are debated, many clinicians recommend a functional ACL brace postoperatively and when cleared for return to sport [19, 25].

In 2014, the American Academy of Orthopaedic Surgeons (AAOS) released a clinical practice guideline (CPG) on the Management of Anterior Cruciate Ligament Injuries [1] and concluded that 'moderate evidence does not support the routine use of functional knee bracing after isolated ACL reconstruction, because there is no demonstrated efficacy', based on three randomised trials [4, 20, 23]. In 2022, the AAOS released an updated guideline and made similar recommendations based on two of the previously referenced randomised trials [2, 4, 20]. Several other organisations have released guidelines with similar conclusions on the use of functional ACL braces. The purpose of this study was to perform a scoping review of CPGs concerning the use of functional ACL braces and to clarify the nomenclature for bracing relevant to ACL injury treatment in order to support prescribing clinicians.

MATERIALS AND METHODS

A PubMed search for CPGs was performed on the topic of ACL injuries with special attention to the use of functional ACL braces. For the purposes of this review, the term CPG was utilised to refer to guidelines developed by organisations based on a literature review in an effort to inform clinical decision-making. The search terms 'anterior cruciate ligament' AND 'clinical practice guidelines' were utilised. Reference lists of relevant articles were reviewed to identify additional guidelines. The original AAOS CPG and reference list were also reviewed [1]. CPGs with sufficient attention to functional braces were included in this scoping review.

Recommendations from the CPGs were summarised with specific attention to parameters for brace use including brace type, period of use following surgery and activities requiring brace use. The references used within the CPGs for support of the specific recommendations were reviewed with special attention to functional ACL braces.

Data from selected supporting references were collected including patient demographics (age, sex and activities/occupation if available), high-risk groups (skeletally immature, hyperlaxity, concomitant meniscal repair, collateral ligament injury, increased sagittal posterior tibial slope and primary versus revision ACL reconstruction), brace protocol and brace use during return to sport. Articles with information on functional bracing for ACL-deficient patients were also evaluated. Additionally, a novel brace that applies a posteriorly directed force to the anterior tibia has been recently described, and guidelines for the use of this dynamic braces. Future studies are, therefore, necessary in order to provide guidance on the use of functional and dynamic ACL braces in high-risk patient populations.

Level of Evidence: Level II.

KEYWORDS

anterior cruciate ligament, functional brace, graft failure, reconstruction

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brace type were reviewed [16]. Due to the loss to follow-up and variable brace compliance during the time of return to sport, a descriptive assessment of study characteristics was performed rather than a formal statistical analysis.

RESULTS

Nomenclature

Three categories of knee braces have been defined by the AAOS including prophylactic bracing, rehabilitation braces and functional braces (Table 1) [3]. A more recently developed fourth category applies a posteriorly directed force to the proximal tibia that changes based on knee flexion angle, and this has been described as a ‘dynamic’ brace [16]; this is in contrast to traditional ‘static’ functional ACL braces that resist tibial translation and rotation with straps but do not apply a flexion-dependent posterior force (Table 1) [11, 16, 29]. Review of clinicaltrials.gov revealed an ongoing study titled ‘Treatment of Acute ACL Injuries in Young Patients Using a Rebound ACL Brace’ (NCT04185532) including two treatment groups: (1) brace with physical therapy and (2) physical therapy alone.

CPGs

Six CPGs developed by professional organisations with specific attention to the use of functional ACL braces met the criteria for inclusion in this scoping review [1, 3, 10, 18, 21, 30]. Three were specifically referred to as ‘Clinical Practice Guidelines’ [1, 10, 18], whereas the other three were individually referred to as ‘ACL Rehabilitation Guidelines’ [30], ‘Practical Clinical Guideline’ [21] and ‘Best Practice Evidence-Based Guideline’ [3], although collectively these six guidelines will be referred to as CPGs for the purposes of this review. Summary statements from the six CPGs concerning the use of braces following ACL reconstruction are listed in Table 2.

Supporting references for CPG recommendations on the use of functional ACL braces

As outlined in Table 2, three studies formed the primary support for CPG recommendations on the use of functional braces following ACL reconstruction [4, 20, 23]. The study by Risberg et al. [23] was cited by all six CPGs [1, 3, 10, 18, 21, 30], Birmingham et al. [4] was cited by three CPGs [1, 10, 30] and McDevitt et al. [20] was cited by a single CPG [1]. Risberg et al. performed a randomised trial with a 2-year follow-up. The treatment group utilised a functional ACL brace for 2–12 weeks after surgery and ‘as needed for sports activities thereafter’ and the comparison group did not receive a brace [23]. McDevitt et al. performed a randomised multicentre study of 100 military academy cadets with a 2-year follow-up comparing treatment with a knee immobilizer used for 3 weeks versus a functional ACL brace used daily for 6 months and ‘for all rigorous activities for at least 1 year’ after surgery [20]. Birmingham

<table>
<thead>
<tr>
<th>Brace category</th>
<th>Key features</th>
<th>Intended use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Knee immobilizer (no hinges)</td>
<td>– Semirigid medial and lateral supports with two to three straps above and below the knee without ability to articulate</td>
<td>– Immediate postoperative period during ambulation with crutches and limited weight-bearing and with postoperative quadriceps weakness</td>
</tr>
<tr>
<td>Adjustable hinged knee brace</td>
<td>– Medial and lateral hinges at the knee connecting rigid stabilisers secured to the limb with two thigh and two leg straps</td>
<td>– Immediate postoperative period during ambulation with crutches and limited weight-bearing and may be used during crutch weaning period</td>
</tr>
<tr>
<td></td>
<td>– Adjustable and lockable hinges that usually range from 10° hyperextension to 120° flexion</td>
<td></td>
</tr>
<tr>
<td>Functional ACL brace</td>
<td>– Rigid hinged brace with thigh and leg straps</td>
<td>– During return to sport after clearance by surgeon and physical therapist, during high impact and pivoting activities during rehabilitation, ACL-deficient patients to protect against further injury, may be considered early after surgical treatment after adequate return of quadriceps function</td>
</tr>
<tr>
<td></td>
<td>– Custom or off-the-shelf</td>
<td></td>
</tr>
<tr>
<td></td>
<td>– Adjustable but not lockable hinges</td>
<td></td>
</tr>
<tr>
<td>Dynamic ACL brace</td>
<td>– Applies a posterior force to the anterior tibia</td>
<td>– Applied acutely after injury for planned nonoperative treatment of ACL tears</td>
</tr>
<tr>
<td></td>
<td>– Rigid hinged brace with thigh and leg straps</td>
<td>– Following ACL reconstruction in high-risk patients</td>
</tr>
<tr>
<td></td>
<td>– Custom or off-the-shelf</td>
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<td></td>
<td>– Adjustable but not lockable hinges</td>
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### Summary of supporting references

The treatment and comparison groups in the three randomised trials which served as the primary supporting references are summarised in Table 3. Special attention was paid to brace type, instructions for use, compliance, study size, demographics, high-risk characteristics, injuries, procedures, subsequent injury, subsequent surgery, collection of patient-reported outcomes, physical examination findings, KT-1000 and isokinetic testing (if performed). All patients in the three randomised trials underwent primary ACL reconstruction with autograft (patellar tendon or hamstring tendon) without collateral ligament reconstruction. Meniscal treatment with repair versus partial meniscectomy was performed if indicated, although there was limited information on meniscal tear type. Based on the age of participants, it is assumed that all were skeletally mature, although this was not specifically reported. Radiographic measurements, including coronal and sagittal plane alignment, were not reported.

### Duration of bracing

The duration and recommendations for brace use in the treatment group (i.e., functional ACL brace) varied...
between the three randomised trials [4, 20, 23]. Risberg et al. required the use of a knee immobilizer for 2 weeks (DonJoy Range of Motion), a functional brace (DonJoy Gold Point) for an additional 10 weeks, and used the functional brace for sports activities thereafter [23]. McDevitt et al. required a hinged knee brace (Donjoy IROM) for 6 weeks, followed by a functional ACL brace (model not specified) for 6 months daily and for all rigorous activities for at least 1 year postoperatively [20]. Birmingham et al. required a functional ACL brace (DonJoy legend) ‘for all physical activities’, and although compliance was reported at 6 and 12 months after surgery, the recommended duration of use was not reported [4].

The duration and type of brace use for comparison groups (i.e., no functional ACL brace) varied between the three randomised trials including no brace [23], knee immobilizer for 3 weeks [20] and a knee sleeve although the prescribed duration was not reported [4]. Recommendations for brace use in the comparison groups (i.e., no functional ACL brace) included either the use of a knee immobilizer daily for 3 weeks with removal two to three times per day during physical therapy [20] or a neoprene knee sleeve for ‘all physical activities…with the potential of adding substantial strain to the knee’ [4].

The recommendations for brace use during activities have been outlined in the preceding paragraphs and in Table 3. Functional ACL braces are designed for use during sporting activities, and many clinicians recommend their use during the first competitive sports season; however, the three randomised trials lack sufficient details regarding use during this time period. As reported in Table 3, there was poor compliance with brace use during the study period and upon return to sports.

**Bracing and age**

Young age is a known risk factor for ACL graft failure and an increased risk of contralateral knee ACL tear, and the use of a functional ACL has been reported to reduce graft failure in adolescent patients in a recent study [22]. The three randomised trials used for the CPGs differed in patient age distribution. McDevitt et al. reported on military academy cadets, and therefore it was assumed that most patients were between 18 and 22 years old, although demographics (age and sex) were not reported [20]. Risberg et al. and Birmingham et al. included patients in the second through fifth decades (with a mean age in the late third decade), and there was a relatively even distribution of males and females within these two studies [4, 23]. A relationship between patient age and subsequent ipsilateral knee ACL tear was not reported, and these studies are not able to provide recommendations for the use of functional ACL braces in paediatric populations.

**Does bracing reduce the risk of rerupture?**

Selected results including subsequent injury or surgery, physical examination, patient-reported outcomes, instrumented laxity and isokinetic testing did not reveal significant differences between the braced and comparison groups in the three randomised trials [4, 20, 23]. However, certain patient subgroups are believed to be at increased risk of graft failure, including young patients (especially skeletally immature) returning to pivoting sports, generalised ligamentous laxity, increased posterior tibial slope and allograft ACL reconstruction [8]. The historical studies by Risberg et al. [23], McDevitt et al. [20] and Birmingham et al. [4] were not designed to allow subgroup analysis of known high-risk patient groups for ACL graft failure, and this is noted in the AAOS CPG updated in 2022 [2]. Additionally, there was insufficient attention to the precise brace protocol and compliance greater than 1 year after surgery, a time when many patients have returned to their intense sporting activity/competition. Finally, the three randomised trials [4, 20, 23] focused only on the surgical treatment of ACL tears, although ACL braces have also been described for the nonsurgical treatment of ACL tears [11, 13, 28].

**DISCUSSION**

The most important finding of this study was the limited evidence available for providing definitive guidance for the use of functional ACL braces in patients following ACL reconstruction, especially at the time of initial return to sport. Importantly, only three studies referenced within the CPGs included the use of functional ACL braces during return to sport following surgery. Of these three randomised trials, there was poor compliance with brace use, especially beyond 1 year after ACL reconstruction, so it was difficult to determine the effect of functional ACL braces on reinjury with return to sport.

A recent clinical study of adolescents who underwent ACL reconstruction reported reduced graft failure in patients who were treated with a functional ACL brace [22]. In another study with a young age group, Hansson et al. reported that the use of a restrictive postoperative rehabilitation protocol in paediatric (age <15 years) ACL reconstruction patients which included a postoperative hinged knee brace and a delayed range of motion progression was associated with a reduced revision rate, although the use of a functional ACL brace was not evaluated in this study [9].
It is important for patients, clinicians and insurers to consider brace nomenclature, and this has been described by the AAOS (Table 1). Extension braces (i.e., knee immobilisers) and adjustable hinged knee braces (i.e., adjustable/lockable postoperative braces) serve to function primarily in the early postoperative period to support the limb during early quadriceps weakness, to support mobility with crutches and to support compliance with range of motion restrictions that may be utilised during ACL reconstruction rehabilitation in patients with additional surgical complexity (e.g., combined ligament reconstruction or select...
Meniscal repairs meniscal tissue, especially during the first few weeks postoperatively.

Most of the studies referenced by the CPGs focused on the early postoperative period, and specifically static extension braces, rather than functional ACL braces. It is important to recognise that an immediate postoperative brace has a distinctly different purpose compared to a functional ACL brace. A functional ACL brace is utilised by many clinicians during return to sport following appropriate post-operative rehabilitation, and some clinicians recommend the use of this brace once a patient is ambulatory.
following surgery as a means of minimising the risk of early ACL graft reinjury. Furthermore, there was insufficient attention to high-risk patient groups and only one randomised trial that specifically considered young females [4].

Collectively, the evidence cited by the six CPGs for recommendation against the routine use of functional ACL braces relies on the results of three randomised trials although a detailed review of these studies reveals important limitations, specifically poor compliance during return to sport as well as limited subgroup analysis in high-risk populations. It is, therefore, important to consult other sources concerning the use of functional ACL braces that demonstrate reduced risk of ACL graft failure. A recent study by Perrone et al. specifically focused on adolescent patients and reported a reduced rate of ACL graft failure in patients treated with a functional ACL brace compared to the nonbraced cohort (2% vs. 12%) [22]. Alpine skiers are another group that may warrant consideration for bracing based on the results that nonbraced skiers were 2.74 times more likely to suffer an ACL graft tear [26].

It is important to consider the results of the CPGs based on the supporting randomised trials and applicability to routine clinical practice. As outlined in Table 3, brace compliance was poor during the critical period of return to sport. Therefore, based on the included studies and guidelines, we believe there is insufficient evidence concerning the use of functional braces to either recommend against their use in clinical practice nor was there sufficient evidence to support recommendations for their use in particular subgroups. However, based on the epidemiological evidence of high-risk groups for graft failure and residual laxity, clinicians may consider the use of a functional ACL brace based on their clinical judgement and shared decision-making with the patient.

A dynamic functional ACL brace which applies a posteriorly directed force to the tibia near extension has been developed since the performance of the three randomised trials on ACL bracing [16, 29]. While initial biomechanical studies have reported lower ACL strain in ACL intact and reconstructed knees along with reduced meniscal strain, clinical studies are necessary to determine whether use of the dynamic brace may decrease the risk of subsequent meniscal injury or ACL graft laxity or failure in select groups.

Several limitations are associated with this scoping review. First, it is possible that the search pattern failed to identify all relevant CPGs on this topic. Additionally, other studies supporting or refuting the use of functional ACL braces may not have been identified using the search technique that relied on the references used for recommendations provided in the CPGs. Limitations within the randomised trials include variable brace protocols, manufacturers and patient compliance. Functional ACL braces may have the greatest influence in high-risk patient groups, and the randomised trials do not provide sufficient detail on these groups or discrete data to allow subgroup comparison. Due to these limitations, clinicians are encouraged to use their best judgement when considering the use of functional ACL braces, especially in high-risk individuals.

**CONCLUSIONS**

Guidance on the use of functional ACL braces following ACL reconstruction is provided in six CPGs supported by three randomised trials. However, the brace protocols and patient compliance in the randomised trials render these CPGs inadequate for providing guidance on the use of functional ACL braces in the general and high-risk patient populations when returning to sport after ACL reconstruction. Functional ACL braces are commonly utilised during the course of ACL injury treatment although there is presently limited evidence supporting or refuting the routine use of these braces. Future studies are, therefore, necessary in order to provide guidance on the use of functional and dynamic ACL braces in high-risk patient populations.

**AUTHOR CONTRIBUTIONS**

Andrew G. Geeslin: Conceptualisation; methodology; formal analysis; data curation; writing—original draft; writing—review and editing. Gilbert Moatshe: Conceptualisation; methodology; formal analysis; data curation; writing—original draft; writing—review and editing. Lars Engebretsen: Conceptualisation; writing—review and editing. Martin Lind: Writing—review and editing. Frida Hansson: Writing—review and editing. Anders Stalman: Writing—review and editing. Bjorn Barenius: Writing—review and editing. Robert F. LaPrade: Conceptualisation; methodology; formal analysis; data curation; writing—original draft; writing—review and editing.

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**CONFLICT OF INTEREST STATEMENT**

Andrew G. Geeslin and Bjorn Barenius have received payment for teaching and presentations for Ossur although not in relation to this manuscript. Robert F. LaPrade is a consultant for Ossur and receives royalties from Ossur. The remaining authors declare no conflict of interest.

**DATA AVAILABILITY STATEMENT**

All data supporting the findings of this study are available within the paper and its Supporting Information.
ETHICS STATEMENT
The present study was a scoping review of deidentified published studies and IRB review and patient consent were performed in the index studies and was not required for this scoping review.

ORCID
Andrew G. Geeslin http://orcid.org/0000-0001-9410-9936

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