

Functional Brace in ACL Surgery

Force Quantification in an In Vivo Study

Robert F. LaPrade,^{*†‡} MD, PhD, Melanie B. Venderley,[†] BS, Kimi D. Dahl,[†] MS, Grant J. Dornan,[†] MS, and Travis Lee Turnbull,[†] PhD

Investigation performed at the Department of BioMedical Engineering, Steadman Philippon Research Institute, Vail, Colorado, USA

Background: A need exists for a functional anterior cruciate ligament (ACL) brace that dynamically supports the knee joint to match the angle-dependent forces of a native ACL, especially in the early postoperative period.

Purpose/Hypothesis: The purpose of this study was to quantify the posteriorly directed external forces applied to the anterior proximal tibia by both a static and a dynamic force ACL brace. The proximal strap forces applied by the static force brace were hypothesized to remain relatively constant regardless of knee flexion angle compared with those of the dynamic force brace.

Study Design: Controlled laboratory study.

Methods: Seven healthy adult males (mean age, 27.4 ± 3.4 years; mean height, 1.8 ± 0.1 m; mean body mass, 84.1 ± 11.3 kg) were fitted with both a static and a dynamic force ACL brace. Participants completed 3 functional activities: unloaded extension, sit-to-stand, and stair ascent. Kinematic data were collected using traditional motion-capture techniques while posteriorly directed forces applied to the anterior aspect of both the proximal and distal tibia were simultaneously collected using a customized pressure-mapping technique.

Results: The mean posteriorly directed forces applied to the proximal tibia at 30° of flexion by the dynamic force brace during unloaded extension (80.2 N), sit-to-stand (57.5 N), and stair ascent (56.3 N) activities were significantly larger, regardless of force setting, than those applied by the static force brace (10.1 N, 9.5 N, and 11.9 N, respectively; $P < .001$).

Conclusion: The dynamic force ACL brace, compared with the static force brace, applied significantly larger posteriorly directed forces to the anterior proximal tibia in extension, where the ACL is known to experience larger in vivo forces. Further studies are required to determine whether the physiological behavior of the brace will reduce anterior knee laxity and improve long-term patient outcomes.

Clinical Relevance: ACL braces that dynamically restrain the proximal tibia in a manner similar to physiological ACL function may improve pre- and postoperative treatment.

Keywords: anterior cruciate ligament injury; anterior tibial translation; ACL brace; functional brace; lower extremity biomechanics

*Address correspondence to Robert F. LaPrade, MD, PhD, Steadman Philippon Research Institute, 181 West Meadow Drive, Suite 1000, Vail, CO 81657, USA (email: drlaprade@sprivaail.org).

[†]Steadman Philippon Research Institute, Vail, Colorado, USA.

[‡]The Steadman Clinic, Vail, Colorado, USA.

One or more of the authors has declared the following potential conflict of interest or source of funding: Össur funded this study and provided unrestricted, in-kind donations of the braces utilized in this study. R.F.L. is a consultant for and receives royalties from Össur, Arthrex, and Smith & Nephew.

Ethical approval for this study was obtained from Vail Valley Medical Center Institutional Review Board.

The Orthopaedic Journal of Sports Medicine, 5(7), 2325967117714242

DOI: 10.1177/2325967117714242

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An increase in knowledge regarding the anatomy and function of the anterior cruciate ligament (ACL) has resulted in more anatomic reconstructions after injury. Additionally, current rehabilitation protocols return patients to range of motion,¹³ weightbearing,¹⁷ and strength-building exercises more quickly after reconstruction.^{8,46} Thus, the ACL reconstruction graft is exposed to forces similar to anatomic loading of the native ACL in the early postoperative period, when the graft is still healing and undergoing remodeling.^{36,43,51} If the reconstruction graft is prematurely exposed to higher loads postoperatively, the result can possibly include graft elongation and failure, functional deficits, residual instability, and an inability to return to sport or prior level of play.[§]

[§]References 2-4, 15, 19, 21, 31, 33, 35, 42, 45, 51.

Functional ACL bracing is an available option, with some surgeons prescribing bracing after ACL reconstructions.¹⁶ The purpose of functional bracing is to provide strain shielding of the graft and kinematic constraint primarily in the anterior-posterior direction, decreasing anterior tibial translation induced by rehabilitation exercises and activities of daily living.^{1,6,7,9,47,50} However, 2 systematic reviews have both reported that postoperative ACL reconstruction bracing does not appear to lessen pain or improve function, rehabilitation, or stability.^{25,40} Furthermore, van Grinsven et al⁵² reported in their systematic review that an accelerated protocol without postoperative bracing has been shown to be advantageous, without leading to stability issues. Thus, most clinical studies do not support the utilization of current functional ACL bracing because it has not been shown to provide the necessary biomechanical stability during more demanding activities^{5,10,14,18} or to improve long-term patient outcomes.^{11,32,34,39}

The native ACL dynamically responds to the flexion angle of the knee and the imposed activity through varying levels of force.⁴⁸ Maximum ACL strain occurs near full extension and then lessens as the knee is flexed to 90°. ^{7,9} Complementing this, quadriceps-focused exercises strain the ACL, while hamstring-focused exercises demonstrate little to no strain on the ACL.⁵ This behavior of the native ACL needs to drive the design of functional ACL braces, but the literature has yet to present a validated brace that appropriately constrains the knee joint and improves long-term patient outcomes because most current ACL braces only provide a static restraint.⁴⁸ Therefore, for surgeons who prescribe bracing after ACL reconstruction, a need exists for a functional ACL brace that dynamically supports the angle-dependent forces of a native ACL, especially in the early postoperative period, to address the limitations of the static-based braces.

The purpose of this study was to quantify the external forces applied to the anterior proximal and distal tibia by both static and dynamic force ACL braces. In particular, the proximal strap forces applied by the static force brace were hypothesized to remain relatively constant regardless of knee flexion angle. In contrast, forces applied by the dynamic force brace to the proximal tibia were hypothesized to dynamically change with regard to flexion angle.

METHODS

This study was approved by the institutional review board at Vail Valley Medical Center, and all participants provided informed consent. Seven healthy adult males (mean \pm SD: age, 27.4 \pm 3.4 years; height, 1.8 \pm 0.1 m; body mass, 84.1 \pm 11.3 kg) participated in this study. Participants had no prior history of knee injury, surgery to the lower extremity, or any other musculoskeletal or neurological condition that would inhibit their ability to perform the required tasks. Three-dimensional kinematic data of the braced limb were collected, along with posteriorly directed forces applied to the anterior tibia at the proximal and distal straps, during 3 movements associated with activities of daily living.

Test Protocol

Participants were fitted with knee braces according to manufacturer recommendations and were allowed unlimited practice; they then performed the following activities, each over an approximately 2-second duration with the audible aid of a metronome: unloaded knee extension, sit-to-stand, and stair ascent. To perform unloaded extension, participants were in a seated position and extended the braced knee from 90° flexion to 0° (full extension). For the sit-to-stand exercise, participants started in a seated position with both knees flexed to 90° and then rose to stand in full extension. The stair-ascent activity required participants to walk up a 3-step flight of stairs. Data from the first (lowest) step were used for analysis.

Functional Braces

Each participant performed the 3 movements twice, once for each brace: a static force ACL brace (Donjoy Armor FourcePoint, DJO Global) and a dynamic force ACL brace (Össur Rebound ACL, Össur Inc). The static force brace had 3 manually adjustable settings corresponding to low, medium, and high brace force. The dynamic force brace was supplied with 3 sizes of torque knobs that corresponded to and resulted in low, medium, and high brace force magnitudes, respectively. For the purposes of this study, the low force setting of the dynamic and static force braces was assumed to produce an equivalent, posteriorly directed force, and likewise for the medium- and high-force settings.

Motion Analysis

Prior to testing, 5 retroreflective spherical markers (10 mm diameter) were placed on the greater trochanter, thigh, knee, shank, and lateral malleolus. The thigh, knee, and shank markers were placed directly on the lateral frame of the brace. For every patient, 1 trial was recorded for each activity at each brace force level. Three-dimensional kinematics were captured using a 10-camera infrared motion capture system (Eagle, Motion Analysis Corp), collecting at 100 Hz.

Pressure Mapping

Adapting a previously reported²⁶ knee brace pressure mapping technique for functional braces, calibrated pressure sensors (Model 4000; area, 27.9 mm \times 33.0 mm; thickness, 0.1 mm; Tekscan Inc) were used to quantify the forces applied by each brace at the anterior proximal and distal tibia straps. The 2 arms of the pressure sensor were individually secured between the proximal and distal brace straps on the anterior aspect of the tibia with separate, thin-profile custom fixtures. The custom fixtures ensured the sensor captured all posteriorly directed forces. The custom fixture and calibrated pressure sensor assembly measurement accuracy was verified with a dynamic load frame (ElectroPuls E10000, Instron) to be within \pm 5% of the indicated force for the force range observed in this study. Pressure data from the sensors were recorded simultaneously

TABLE 1

Proximal and Distal Brace Forces During Each Exercise: Mean Posteriorly Directed Forces Applied by the Dynamic Force and Static Force Braces at the Anterior Tibia Corresponding to Each Force Setting (Low, Medium, and High)

Activity	Strap	Brace	Brace Force, N, Mean \pm SD		
			Low Setting	Medium Setting	High Setting
Unloaded extension 30°	Proximal	Static force	9.9 \pm 7.6	8.0 \pm 6.8	12.4 \pm 3.9
		Dynamic force ^a	70.7 \pm 17.4	77.4 \pm 20.0	92.5 \pm 22.5
	Distal	Static force	18.8 \pm 7.7	20.8 \pm 10.6	23.1 \pm 13.3
		Dynamic force ^b	11.6 \pm 4.5	6.7 \pm 4.7	4.6 \pm 3.4
Sit-to-stand 30°	Proximal	Static force	10.1 \pm 7.2	7.5 \pm 6.1	10.9 \pm 4.3
		Dynamic force ^a	51.6 \pm 12.1	56.1 \pm 11.9	64.7 \pm 19.9
	Distal	Static force	10.5 \pm 4.9	9.8 \pm 2.8	11.6 \pm 7.2
		Dynamic force ^b	6.2 \pm 2.9	3.8 \pm 2.5	1.9 \pm 1.4
Stair ascent 30°	Proximal	Static force	13.0 \pm 9.5	9.9 \pm 7.4	12.8 \pm 6.4
		Dynamic force ^a	53.6 \pm 13.2	56.3 \pm 14.1	58.9 \pm 11.6
	Distal	Static force	13.8 \pm 7.1	13.7 \pm 2.1	13.9 \pm 5.9
		Dynamic force ^b	8.5 \pm 3.4	6.6 \pm 3.3	4.3 \pm 2.4

^aThe proximal strap of the dynamic force brace applied significantly more force than that of the static force brace across all force settings ($P < .001$).

^bThe distal strap of the dynamic force brace applied significantly less force than that of the static force brace across all force settings ($P < .001$).

with the motion capture data at a rate of 100 Hz using the corresponding software (I-Scan, Tekscan Inc).

Data Reduction

Synchronous motion capture and force data were used to determine the posteriorly directed force as a function of knee flexion. The data were analyzed from 90° to 0° (full knee extension) in 15° intervals using a custom algorithm (MATLAB, Mathworks).

Statistical Analyses

A power calculation was made post hoc for the primary comparison of braces at 30° of flexion. Assuming a simplification of the full analysis (paired comparison of means) and 2-tailed testing with an alpha of .05, 7 patients were sufficient to detect an effect size of $d = 1.27$ with 80% statistical power. Two-factor linear mixed-effects models using brace type and force level as within-participant (repeated measures) factors were constructed to compare mean proximal and distal forces during each of the 3 movements at 30°. The Tukey method was used to make post hoc pairwise comparisons. All statistical analyses were performed with the statistical package R (R Development Core Team; with package *ggplot2*).^{22,37,38,54}

RESULTS

The forces applied to the proximal and distal tibia by the static force and dynamic force braces for all 3 exercises, at all 3 force settings, are reported in Table 1. Force comparisons were made and the results are presented for 30° of flexion, where the ACL experiences higher in vivo forces.⁴⁸

Unloaded Extension

During unloaded extension, the mean posteriorly directed force applied to the proximal tibia at 30° of flexion by the dynamic force brace (80.2 \pm 21.2 N) was significantly larger than the force applied by the static force brace (10.1 \pm 6.2 N, $P < .001$), across all 3 force settings. Regardless of brace type, the posteriorly directed force applied to the proximal tibia was significantly different between the high and low force settings ($P = .029$). Figure 1A shows the mean posteriorly directed force at the proximal tibia during unloaded extension for both braces as a function of flexion angle at each force setting. The mean posteriorly directed force applied to the distal tibia at 30° of flexion by the dynamic force brace (8.0 \pm 5.0 N) was significantly less than the force applied by the static force brace (20.9 \pm 10.4 N, $P < .001$), across all 3 force settings (Figure 1B).

Sit-to-Stand

During sit-to-stand, the mean posteriorly directed force applied to the proximal tibia at 30° of flexion by the dynamic force brace (57.5 \pm 15.4 N) was significantly larger than the force applied by the static force brace (9.5 \pm 5.9 N, $P < .001$), across all 3 force settings. Figure 2A shows the mean posteriorly directed force at the proximal tibia during sit-to-stand for both braces as a function of flexion angle at each force setting. The mean posteriorly directed force applied to the distal tibia at 30° of flexion by the dynamic force brace (4.0 \pm 2.8 N) was significantly less than the force applied by the static force brace (10.6 \pm 5.0 N, $P < .001$), across all 3 force settings (Figure 2B).

Stair Ascent

During stair ascent, the mean posteriorly directed force applied to the proximal tibia at 30° of flexion by the dynamic

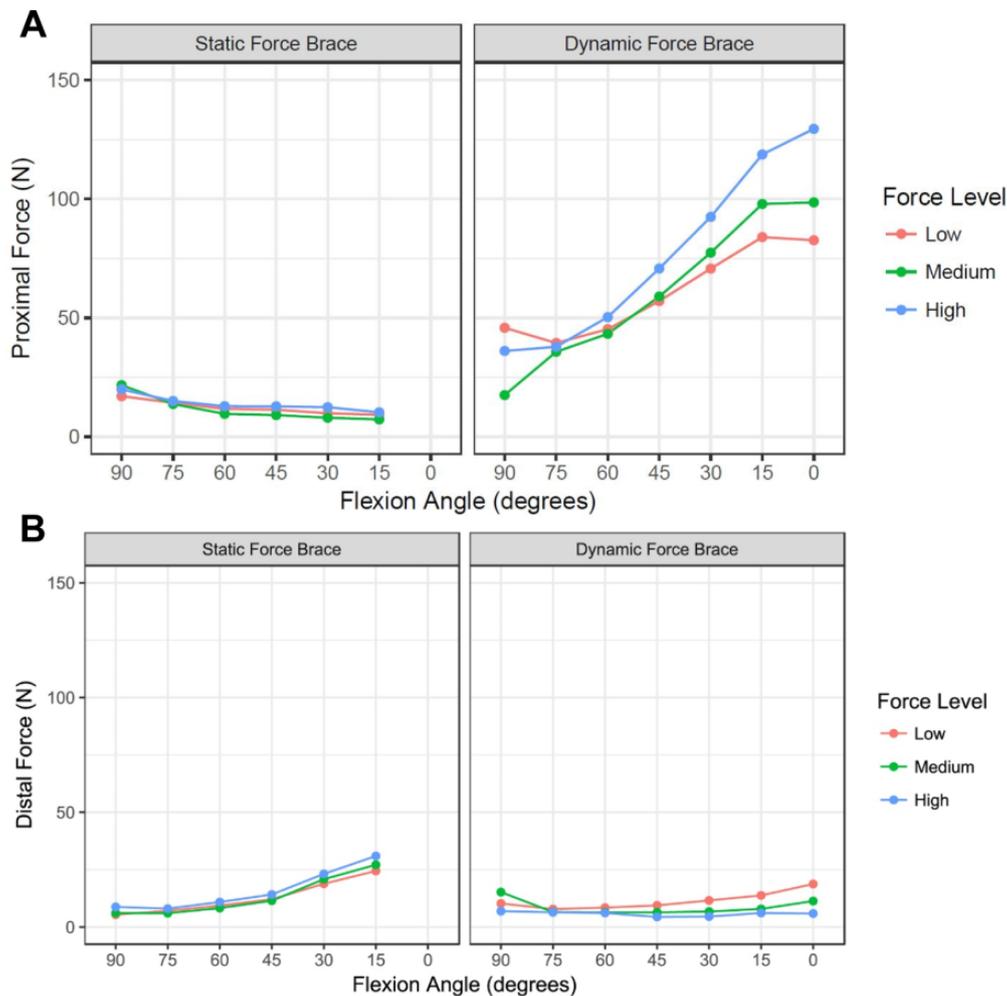


Figure 1. Mean posteriorly directed force applied by each brace to the (A) proximal and (B) distal tibia during unloaded extension as a function of flexion angle at each force setting.

force brace (56.3 ± 12.5 N) was significantly larger than the static force brace (11.9 ± 7.6 N, $P < .001$), across all 3 force settings. Figure 3A shows the mean posteriorly directed force at the proximal tibia during stair ascent for both braces as a function of flexion angle at each force setting. Note that participants did not consistently reach the limits of the full range of knee flexion; therefore, Figure 3 presents only a limited range of flexion (15° - 60°). The mean posteriorly directed force applied to the distal tibia at 30° of flexion by the dynamic force brace (6.5 ± 3.4 N) was significantly less than the force applied by the static force brace (13.8 ± 5.2 N, $P < .001$), across all 3 force settings (Figure 3B).

DISCUSSION

The most important finding of the study was that the force applied at the proximal tibia by the dynamic force brace dynamically changed as a function of flexion angle, consistent with physiological ACL forces. The results of the study confirmed the hypothesis that forces applied by the

static force brace at the proximal tibia would remain relatively constant regardless of flexion angle and that forces applied by the dynamic force brace at the proximal tibia would dynamically change with regard to flexion angle. Forces applied at the proximal tibia by the dynamic force brace were significantly higher and physiologically relevant compared with those by the static force brace at 30° of flexion during unloaded extension, sit-to-stand, and stair ascent.

The ACL experiences dynamic in vivo forces, which correspond to changing flexion angles.⁴⁸ Current functional static force ACL braces only provide a relatively constant force, regardless of knee flexion angle, and have been shown to be largely ineffective in restoring stability at high loads.^{5,10,14,18} Mayr et al³² demonstrated that a stabilizing knee brace after ACL reconstruction was not advantageous compared with treatment without a brace at 4-year follow-up. However, according to Dubljanin-Raspopović et al,¹⁸ functional ACL braces have been reported to provide the necessary joint stability at low clinical loads. Because current bracing techniques not proven to be able to apply

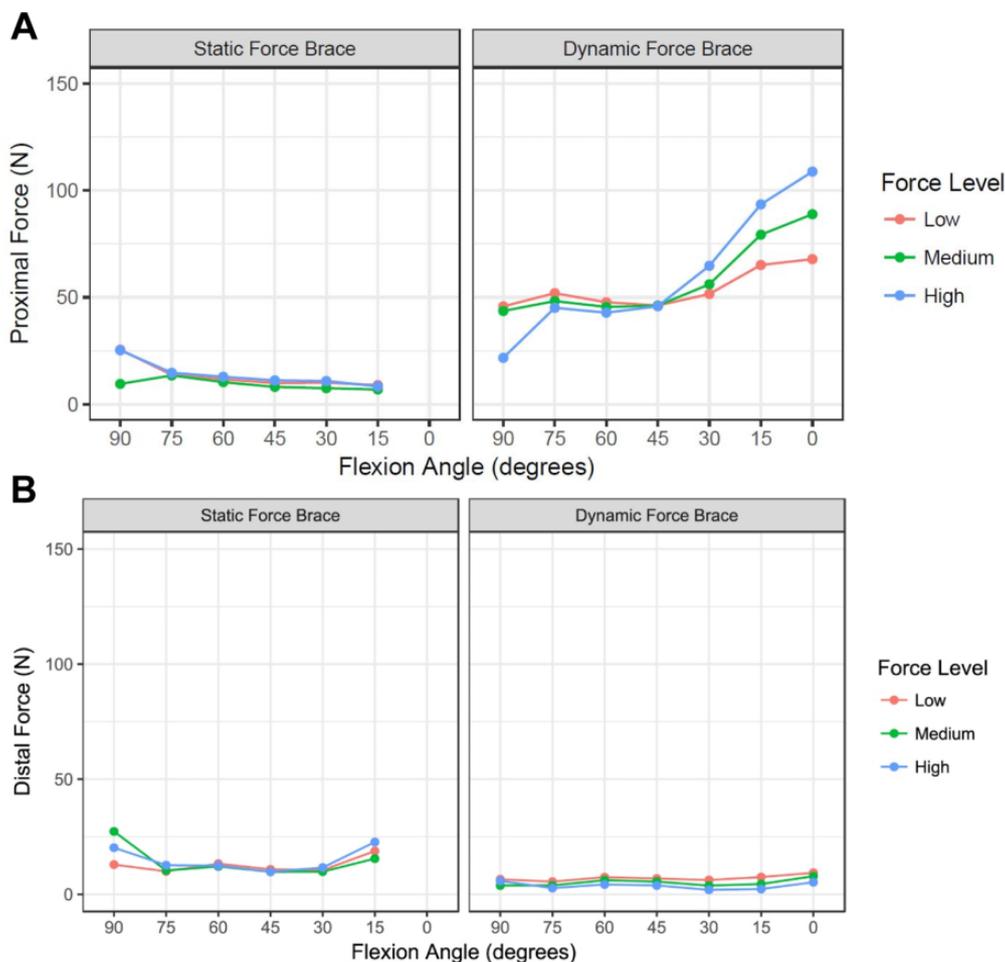


Figure 2. Mean posteriorly directed force applied by each brace to the (A) proximal and (B) distal tibia during sit-to-stand as a function of flexion angle at each force setting.

higher loads, a brace that provides increased protection of an ACL reconstruction graft is still desired postoperatively.

In addition, a dynamic force brace would be helpful in cases where the ACL may be anatomically or biologically compromised. Anatomic factors that can place extra stress on an ACL graft include an increased posterior tibial slope^{28,53} and patients with genu recurvatum and soft tissue (hamstring) graft reconstructions.²⁴ When allografts are utilized during ACL reconstruction, poor graft strength due to sterilization and delayed graft incorporation from an immune response⁴⁴ can result in increased laxity.⁴⁹ Thus, higher revision rates have been reported for allografts versus autografts.³⁰ In addition, if failure does occur, revision ACL reconstruction can have delayed graft incorporation and healing,¹² which could place the graft at risk for early elongation or failure.²⁰ In all these cases, a dynamic force functional brace may protect a compromised ACL graft from fatigue failure.

Compared with the static force brace, the dynamic force brace tested in this study applied higher, more physiologically relevant, posteriorly directed loads to the proximal tibia at 30° of flexion, where the *in vivo* forces of the native ACL have been shown to be among the highest (Figure 4).^{29,41,48}

This is theorized to improve stability during rehabilitation, which can otherwise place higher demands on the healing reconstruction graft.^{8,46} To the authors' knowledge, no previous study exists that validates a brace that matches the angle-dependent forces of the native ACL. Importantly, a functional brace capable of providing dynamic forces, which are more physiologically equivalent when the ACL is at maximum elongation (ie, between full extension and 30° of flexion), may reduce graft laxity and potentially improve overall patient outcomes.^{23,27} The results of the present study indicated that proximal and distal strap forces were significantly higher and significantly lower, respectively, for the dynamic force brace compared with the static force brace during all 3 exercises at 30° of flexion. The unique design intricacies of the individual braces may have caused the observed data trends. Notably, the authors theorize that the ideal location of posteriorly directed force application to the tibia by an ACL brace is immediately distal to the knee joint line (proximal strap location) and at lower flexion angles where the ACL experiences higher *in vivo* forces.⁴⁸ The results of the present study indicated that the dynamic force brace consistently

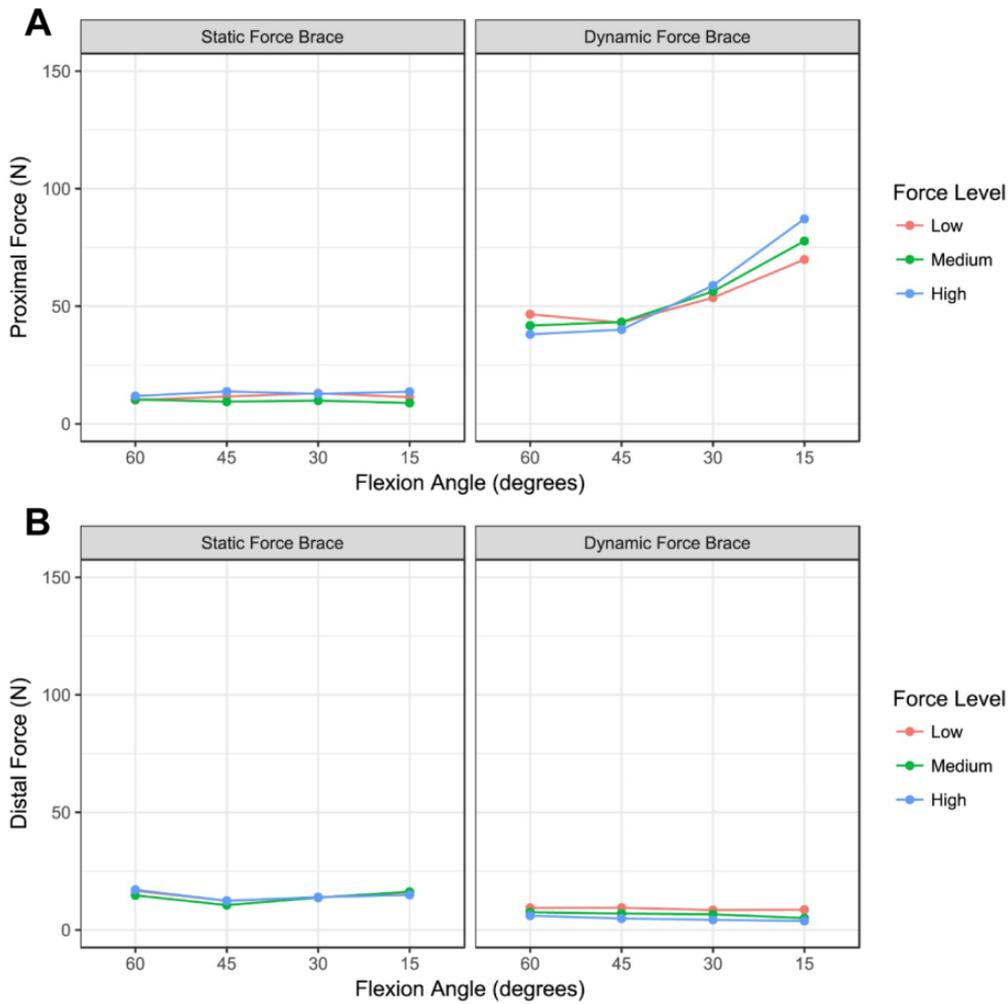


Figure 3. Mean posteriorly directed force applied by each brace to the (A) proximal and (B) distal tibia during stair ascent as a function of flexion angle at each force setting.

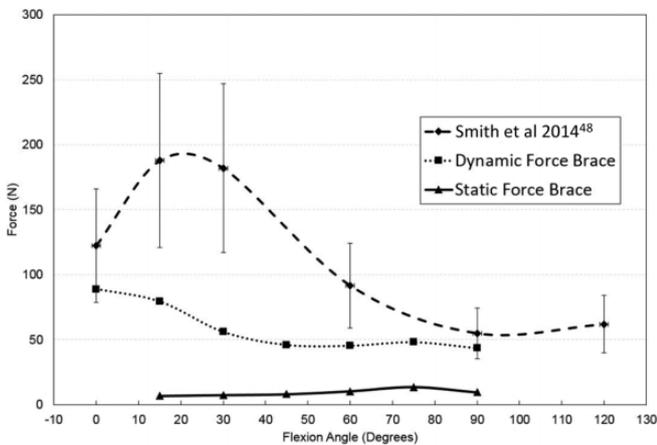


Figure 4. Mean posteriorly directed proximal force applied by each brace during sit-to-stand at force level 2 compared with previously published⁴⁸ mean anterior-posterior in vivo anterior cruciate ligament forces.

applied significantly larger, physiologically relevant proximal strap forces than the static force brace. In contrast, and with less theorized clinical utility, the static force brace applied significantly larger, relatively small-magnitude, distal strap forces than the dynamic force brace.

This present study did have some limitations. First, only asymptomatic, male patients were utilized for testing. However, the overall relationship between force and flexion angle is believed to remain the same between males and females due to the mechanical nature of the braces. The study was also completed in a controlled laboratory environment, which encompassed neither higher intensity activities nor associated problems with bracing over extended periods of activity in which the thigh soft tissue leads to posterior brace migration. Nevertheless, this reproducibility allowed for brace comparison with activities commonly associated with postoperative ACL rehabilitation. Moving forward, further studies are recommended to determine whether the use of a dynamic force brace will improve long-term patient outcomes after ACL reconstruction.

CONCLUSION

The dynamic force brace, compared with the static force brace, applied significantly larger posteriorly directed forces to the anterior proximal tibia in extension, where the ACL is known to experience larger in situ forces. Further studies are required to determine if the physiological behavior of the brace will reduce forces on the ACL graft and lead to decreased anterior knee laxity and improved long-term patient outcomes.

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