The role of functional knee bracing, particularly following anterior cruciate ligament (ACL) reconstruction, continues to be debated. The results of previous testing have been equivocal but, for the most part, have demonstrated that functional knee bracing provides increased mechanical stiffness to the knee under low physiologic loads. One of the principal criticisms of characterizing the effect of functional knee bracing on anterior tibial translation is that prior testing has used inappropriate models or subphysiologic loads.

A number of different methods have been used to characterize the effects of functional knee braces. Cadaveric models have been used, but this model suffers from several significant limitations, not the least of which are the variable compliance of the soft-tissue interface and the inability to perform repetitive high-load testing without altering the material response of the specimen. Knee arthrometers have also been used extensively in the functional knee brace evaluation.

Aside from the subphysiologic loads applied with knee arthrometers, the anterior interface of the arthrometers on the limb was impinged by the brace structure, negating the accuracy of arthrometer measurement. Other methods involving electromyography, force platform analysis, motion analysis, stereoradiographic techniques, and dynamometer analyses have produced variable and often contradictory results.

One alternative for standardization of functional knee brace testing is the use of a mechanical surrogate. Although mechanical surrogates are not representative of normal limb kinematics or physiology, they offer some substantial benefits for characterization of functional knee brace performance. Mechanical surrogates use a standardized interface between brace and limb thus equalizing the effects of material properties on brace performance. Furthermore, mechanical surrogates provide consistent, repeatable loaded response, insuring test-retest reliability.

This investigation used a sophisticated dynamic mechanical surrogate to compare the loaded response of off-the-shelf and custom-made functional knee braces for the control of anterior tibial translation under physiologic levels of load.

**MATERIALS AND METHODS**

One off-the-shelf and one custom-made and off-the-shelf functional knee orthoses from four manufacturers were evaluated. Anterior tibial translation testing was performed using a pneumatic mechanical surrogated knee. The mechanical surrogate was interfaced with a servohydraulic materials testing system, which applied all anterior/posterior displacements to an ultimate anterior load of 400 N. Comparison of the individual custom versus premanufactured braces showed that the custom braces demonstrated a statistically significant difference for restraining anterior displacement ($P = .0001$ to $P = .0005$). Pooled data from all tests showed that the custom brace measurements as a group restrained anterior displacement better than the premanufactured brace group by a mean difference of $0.84$ mm ($P = .0001$). The authors question whether such small, sub-millimeter findings between custom and off-the-shelf functional derotation braces represent any clinically significant differences.

Custom-Fit Versus Premanufactured Braces

CHARLES A. SOMA, MD; PATRICK W. CAWLEY, DSC, OPA, RT; STEPHEN LIU, MD; C. THOMAS VANGSNESS, JR, MD
made functional knee brace were obtained from each of four manufacturers. Molds of a surrogate limb were made by certified orthotists for all custom-made orthoses in this investigation. Off-the-shelf braces were obtained using circumferential measurements of the surrogate limb taken at the joint line, 6 inches above and below the joint line. The following braces were used: 1) CTI (custom) and MVP (off-the-shelf) (Innovation Sports, Irvine, Calif); 2) Defiance (custom) and GoldPoint (off-the-shelf) (Smith & Nephew DonJoy, Carlsbad, Calif); 3) Townsend Custom Functional Knee Brace and Off-the-Shelf Brace (Townsend Design, Bakersfield, Calif); and 4) Performer (custom) and Controller (off-the-shelf) (Orthopedic Technology Inc, Tracy, Calif).

Testing was performed using a pneumatically actuated mechanical surrogate of the right lower limb (Figure 1). In the surrogate model, the major ligaments, quadriceps, and hamstring mechanisms were represented using teflon-coated stainless steel cables, which were interfaced in series with pneumatic actuators. In this model, anterior displacement of the tibia was closely approximated those of the cadaveric model. This mechanical surrogate also incorporated meniscal analogs constructed of Delrin engineering polymer (E.I. duPont de Nemours & Co, Wilmington, Del). The menisci interfaced with the medial and lateral tibial plateau via machined posts, which were interfaced with a series of nested springs and elastomer bands about the periphery of the medial and lateral tibial plateau.

Soft-tissue analogs of the thigh and calf musculature were constructed of a homogeneous urethane elastomer (TC-274; BBJ Enterprises, Garden Grove, Calif). This material was chosen as it provided a resilient interface for the braces and had excellent repeatable recovery characteristics following loading.

The mechanical surrogate was interfaced with a servohydraulic materials testing system (MTS, Eden Prairie, Minn) for application of anterior/posterior shear forces. Loads were applied through a compliant load-link positioned at the tibial tubercle (Figure 2). The MTS was operated in the load control mode and quantified all applied loads and displacements during testing. Data on displacement, rate of displacement, and load were acquired as functions of time using a computerized A/D data acquisition system at a sampling rate of 200 Hz. Compliance in the mechanical surrogate under load was quantified using a digital micrometer (Mitutoyo, Japan) interfaced with the femur analog. Correction factors for femoral component displacement/system compliance, actual values for applied load, displacement offsets, and system preload were calculated for each trial.

With the mechanical surrogate positioned in the MTS, the unbraced limb was subjected to five calibration loading cycles to a peak load of 200 N while data was acquired. The limb was first loaded anteriorly followed by an equal posterior “setting” force to return the knee to its resting position. Loading of the unbraced limb was conducted at only half the peak load for braced tests because, without contiguous soft tissue of joint capsule, anterior dislocation of the unbraced knee was possible at loads >200 N. Following five unbraced loading cycles, a brace was randomly selected and applied to the limb in strict accordance with manufacturer instructions. Straps on all braces were tensioned at 44 N using a spring tensiometer to provide consistency across all braces. This tension level was based on unpublished trials in our laboratory to evaluate patient comfort levels.

Following brace application, the limb was cycled five times without data acquisition to allow the brace to equilibrate on the limb. Five subsequent cycles were performed with data acquisition. The
unbraced limb was always tested before brace application to insure calibration of the system. Anterior displacement forces up to 400 N were applied to each brace specimen at a rate of 666.75 N/sec. Five trials at each test condition were conducted for each brace.

An analysis of variance was performed to identify between and within group differences. Where a large difference was identified, Tukey’s Studentized Range test was performed to further evaluate the differences.

RESULTS

Calibration trials run in between brace tests showed consistent anterior tibial displacement by the surrogate knee apparatus and servohydraulic testing machine. Reproducible loading and unloading curves were consistently observed with this testing apparatus at these loads. Plots of displacement versus applied load for all braces are shown in Figure 3, generally showing a linear curve to 400 N of applied load.

Comparison of individual brace pairs revealed that for all pairs a statistical difference was noted with custom braces controlling anterior displacement better than the premanufactured brace group by a mean difference of 0.84 mm ($P=0.0001$).

DISCUSSION

This investigation demonstrated that all braces tested provided a substantial increase in the anterior mechanical stiffness of the limb under physiologic loading. Although differences between custom-made and off-the-shelf braces were statistically significant, these differences were $<1$ mm for all braces. This miniscule difference suggests that both brace types provide adequate resistance to anterior tibial translation under physiologic levels of load. It also suggests that, for most indications, off-the-shelf braces may be an adequate alternative to the typically more expensive custom-made braces. Custom-made braces may have more use when unusual morphologic requirements are present or higher strength is required.
Based on the favorable subjective response reported in the literature, the physiologic effect of functional knee braces is probably multidimensional in nature. Design and material issues such as surface area, limb-contact area, and material properties of the brace structure all contribute to the composite material response when the limb is braced. A number of investigations have demonstrated that functional knee bracing effects may be more than purely mechanical and have shown beneficial effects of bracing on neurosensory function in the lower extremity. As Dye noted, the knee is a biologically complex structure in which restoration of full preinjury status is multidimensional, involving not only mechanical reconstruction of damaged soft tissues but also restoration of physiologic function. Functional knee bracing may play a role in restoration of functional status, but bracing should be considered only an adjunct to a multidimensional program addressing all aspects of physiologic function.

REFERENCES