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The effects of thigh soft-tissue stiffness on the control of anterior tibial displacement by functional knee orthoses

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Abstract—Using three soft-tissue analogs of variable compliances, four custom functional knee orthoses were evaluated for their abilities to control anterior tibial displacement (ATD) using an anterior cruciate ligament (ACL)-deficient surrogate knee model with applied forces from 25 to 250 N. These analogs had stiffnesses (compliance^{-1}) ranging from 2.18 N/mm to 4.6 N/mm, simulating the range in the thigh soft-tissue compliances found in subjects ranging from sedentary individuals to competitive athletes. Significant differences in the ATDs allowed were observed between the soft-tissue analogs, orthoses, and the force applied. At low forces, soft-tissue compliance did not play an important role in the reduction of ATD; however, at high forces ATD was directly related to the soft-tissue compliance.

Key words: *anterior tibial displacement, custom functional knee orthoses, soft-tissue compliance.*

INTRODUCTION

Many studies, as well as reviews, have compared functional knee orthoses with respect to resistance to anterior tibial displacement (ATD) in the anterior cruciate ligament (ACL)-deficient knee (1–5). Although the bilateral hinge-post-shell design has repeatedly been shown to provide the greatest degree of resistance to tibial translation (1,5,6), many other factors, including specific design and materials as well as patient physique, affect the efficacy of these orthoses. Soft-tissue composition and compliance of the thigh have been inferred as important factors affecting orthosis resistance to tibial translation by several authors (1,4,5), but the precise effect and degree that this variation in soft tissue has on orthosis function has not been specifically studied. Because thigh tissue compliance varies tremendously between patients with different physiques, ACL-deficient versus ACL-intact, both in terms of tissue composition and muscle conditioning post-injury, it is reasonable to assume that both choice of orthosis and its design will vary depending on which patient population is targeted for treatment. The purpose of this study is to examine the effect of thigh soft-tissue compliance on control of ATD by custom functional knee orthoses.

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METHODS

Orthoses

Four custom functional knee orthoses were evaluated (**Figure 1**):

1. The Performer, Orthopedic Technology, Inc., San Leandro, CA 94577 (Orthotech)
2. Townsend Custom, Townsend Design, Bakersfield, CA 93309 (Townsend)
3. DonJoy Custom 2000, Smith and Nephew DonJoy Inc., Carlsbad, CA 92008-6601 (DonJoy)

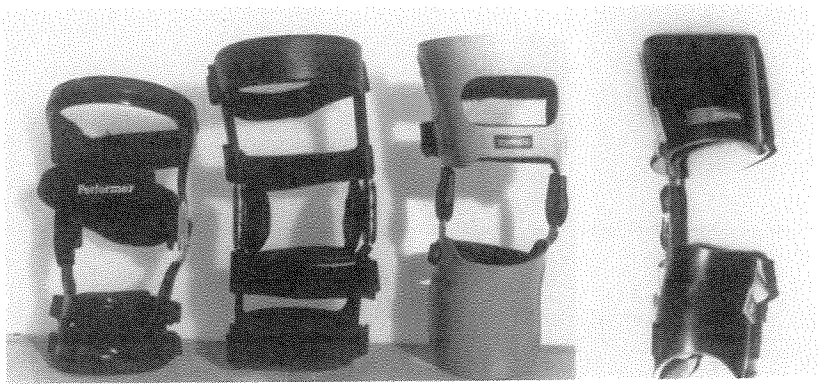

Figure 1.
Four custom functional knee orthoses: from left to right, the Performer, DonJoy, Townsend, Poly-Axial.

4. Poly-Axial Knee Cage, Generation II USA, Inc., Bothell, WA 98011 (Poly-Axial).

All manufacturers advertise that their orthoses resist or restrain ATD in knees with ACL problems. Manufacturers donated their knee orthoses for testing. Fitting of each orthosis strictly followed manufacturer criteria.

Surrogate Knee

Each component of the surrogate leg consisted of a rolled rectangular steel core with a surrounding rigid foam cast of the leg of a 69 in (1.75 m), 150 lb (68 kg), 28-year-old male runner (**Figure 2**). The mechanical rigidity of each knee orthosis was tested in the sagittal plane of the surrogate knee with the femoral component fixed in space and the tibial/ankle component freely moving in that plane (**Figure 3**). The surrogate knee joint was set at 20 degrees of flexion, the position of maximum knee laxity in the sagittal plane (7). The tibial component could freely slide anteriorly relative to the femur at the level of the tibial plateau to a maximum distance of 27 mm. A hinge at the ankle portion allowed application of a posteriorly directed force at the ankle to produce anterior motion of the tibial component. A tensiometer (Dilon Force Gauge, Camarillo, CA) was employed to measure the applied force at the ankle, and a linear displacement scale (Starret, Athol, MA) was used to measure the ATD.

Soft Tissue

Each tissue substitute consisted of three layers of foam glued together with rubber cement. The resulting rectangular foam sheet was 19-mm thick. Duct tape attached each tissue substitute circumferentially around the immobile femoral component of the surrogate knee. The least compliant soft tissue was constructed using a rigid foam-core thigh covered with PPT (Professional Protective Technology, Langer Biomechanicals, Deer Park, NY) and Spenco (Spenco neoprene soft cushion product, Spenco Medical, Waco, TX) to approximate the soft-tissue hardness of a well-conditioned athlete (soft tissue A). Two soft-tissue analog shells (denoted as soft tissues B and C) were constructed using combinations of soft and rigid foam layers.

The compliance (stiffness^{-1}) of the human thigh soft tissue, 7 cm above the knee joint, was measured for 10 (5 female, 5 male) competitive college athletes with an average age of 20 yrs (17–23), 10 (5 female, 5 male) recreational athletes with an average age of 30 yrs (25–35), and 10 (5 female, 5 male) sedentary subjects with an average age of 45 yrs (34–55). The sedentary individuals reported little or no routine athletic activity or exercise. The recreational athletes used in this study are defined as individuals who participate in aerobic exercise for at least one-half hour three times a week. Competitive athletes used in this study participated in college sports. Measurements of the quadriceps were taken during both muscle contraction and relaxation. For the relaxed state, all participants were in a sitting position with the hips and knees in 90° and the feet making contact with the floor. For the contracted state, all participants stood in a semi-squat position with their backs against the wall and their hips and knees at 45°.

The stiffness of the surrogate limb soft-tissue analog and human-subjects' thigh soft tissue was measured with a custom ring transducer in series with a linear variable differential transducer (LVDT) to measure displacement.

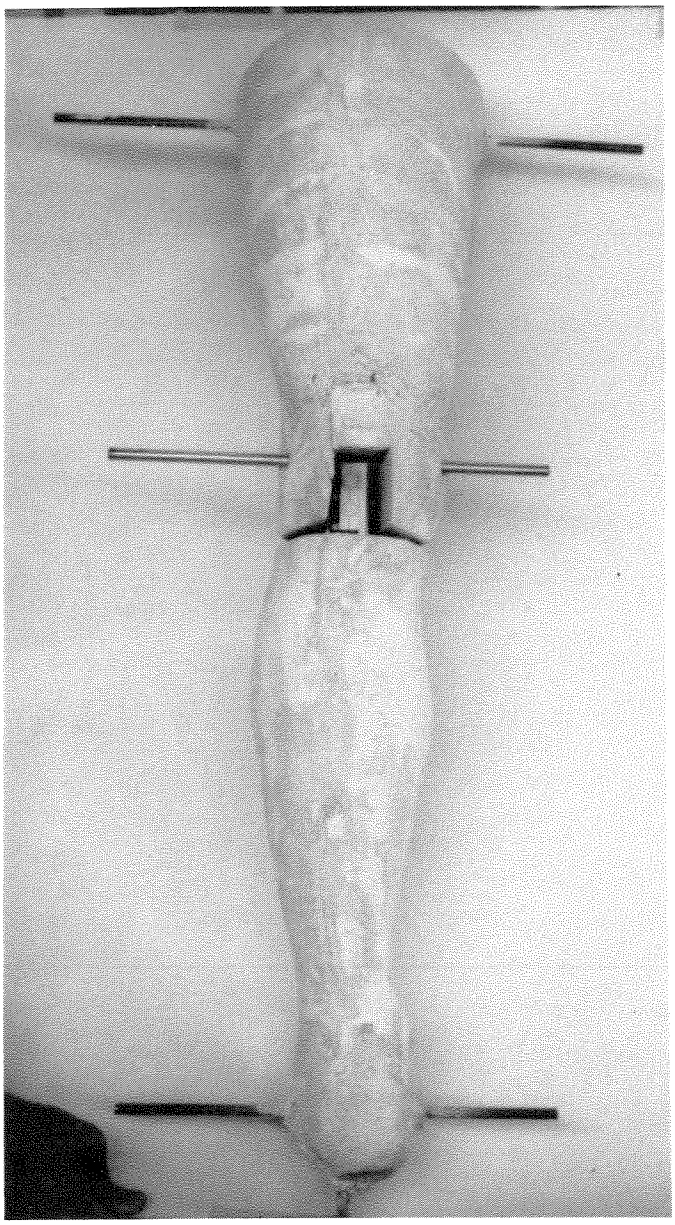

Figure 2.
Surrogate leg.

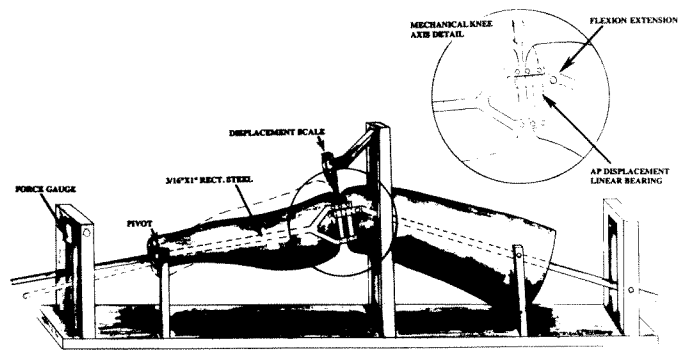

Figure 3.
Surrogate leg with attached force gauge, displacement scale, and a close-up view of the mechanical knee joint.

The compliance of the LVDT was negligible. A 0.25-in (1.22 cm) diameter, flat-faced plunger was used as the indenter in all cases. The housing of the LVDT was held rigid while the force handle drove the LVDT core, with the indenter attached, into the simulated tissue. A maximum force of 20.0 N was used in all cases. The force and displacement data were recorded simultaneously via computer and saved for later analyses. The stiffness of the soft tissue was determined by computing the slopes of the displacement versus applied force plots, using standard linear regression. All relationships between force and displacement were observed to be linear (R>0.9). A least squares linear regression was performed to obtain the slope of the force-displacement line, which is equivalent to the stiffness of the material. For the surrogate limb, 4 tissue measurements were made at circumferential locations 7 cm above the knee joint and 5 cm below the joint line at the tibia; the stiffness values were averaged for each location. The same apparatus was also used to measure the compliance of the thigh soft tissue of the volunteers in the relaxed and contracted states.

Experimental Procedure

The soft-tissue analog (A, B, or C) was randomly selected and attached circumferentially to the surrogate knee femur with duct tape. Fitting of each orthosis to the surrogate knee with attached tissue substitute followed manufacturer guidelines. After proper placement, the straps were tensioned to 44.5 N (10 lbs), except for elastic straps which were hand-tightened.

Prior to each test, the surrogate leg was cycled five times through its full range of anterior/posterior tibial motion. The randomly selected orthosis was then applied to the surrogate limb. The application of the orthosis and strap tightening was completed with strict adherence to manufacturer recommendations. Anterior tibial forces ranging from 25 to 200 N were then applied at 25-N increments and the tibial displacement was recorded at each force. Using this sequence, each orthosis was tested 11 times for each soft-tissue analog. After each trial, the orthosis was repositioned on the knee and the straps were retightened as outlined above.

The ATD at each applied force was recorded. When the knee registered its maximum ATD of 27 mm, the trial ended. The entire sequence of 11 trials was repeated for the Orthotech, Townsend, Poly-Axial, and DonJoy orthoses (in random order). Following the testing of all these orthoses, the soft-tissue analog was removed and a different soft tissue was attached around the surrogate knee. The above testing sequence was repeated again for the four orthoses in random order. All three soft-tissue analogs were tested with all four orthoses. ATD values were recorded and compared for all the orthoses, with each soft-tissue analog at all the forces.

Statistical Analysis

For each orthosis, 11 values were obtained for ATD at each force using each tissue substitute. From this data, a mean ATD at each force was calculated. A two-way analysis of variance (ANOVA) by orthosis make and tissue substitute was performed on these means. The results of this two-way ANOVA allowed for a comparison of total mean ATDs using different soft-tissue substitutes. We also performed a one-way ANOVA by orthosis make at 100 N applied force and then performed a multiple pairwise comparison using the Student-Newman-Keuls method. This allowed for a comparison of the mean ATD for each orthosis while keeping tissue conditions constant. Comparisons were made for athletes, recreational athletes, and sedentary subjects in both the relaxed and contracted states. Furthermore, the femoral soft-tissue stiffness of the surrogate limb and the human subjects was compared. All statistical analyses were performed by the statistical computer package, SigmaStat, at a p level of 0.05.

RESULTS

Table 1 shows the average compliance of soft-tissue analogs and the human subjects. The three soft-tissue substitutes are denoted as A, B, and C and range from least to most compliant (A=4.6 N/mm, B=3.26 N/mm, and C=2.18 N/mm; in all cases $p<0.05$). The thigh soft-tissue stiffness of the sedentary individuals averaged 1.43 N/mm (relaxed) and 2.05 N/mm (quadriceps contraction). The recreational athletes showed thigh soft-tissue stiffness of 1.56 N/mm (relaxed) and 2.84 N/mm (contracted). The competitive athletes showed thigh stiffness of 1.71 N/mm (relaxed) and 3.28 N/mm (contracted). There was a significant difference in the contracted compliance of the three groups in the contracted state ($p<0.01$), but not during relaxation ($p=0.59$).

Figures 4 and **5** show the displacement that each orthosis allowed versus the applied forces using each of the three different soft-tissue substitutes. In general, at higher forces the less compliant the soft-tissue analog, the less displacement allowed by the orthosis.

At low forces, the Poly-Axial orthosis (**Figure 4**) showed significant differences in ATD between soft-tissue analogs A, B, and C. At forces higher than 75 N, ATD correlated directly with the compliance of the soft-tissue analogs. At 125 N and above, this orthosis could not be tested further, having reached the apparatus maximum ATD of 27 mm.

For the Performer (**Figure 4**), significant variations in ATD for the three soft-tissue analogs were observed only at forces greater than 125 N. Using the soft tissue A, the least compliant, the Performer showed more ATD than with the more compliant soft tissue B at all forces up to 150 N. Beyond this force, however, soft tissue B allowed full-scale displacement, whereas the soft tissue A did not displace to full scale until forces were greater than 200 N. At no force did soft tissue B allow more displacement than soft tissue C.

The DonJoy orthosis (**Figure 5**) showed no significant difference in displacements between soft tissues B and C until forces of 150 N were applied. At all forces above 150 N, the displacement differences between all three groups were significant to at least $p<0.05$.

The Townsend custom orthosis (**Figure 5**) showed an increase in average tibial displacement with decreasing

Table 1.
Soft-tissue compliance of soft-tisue analogs (a, b, c) and human subjects.

Soft-Tissue Analog (N/mm)	(p<0.05)	
A	4.6 ± 0.28	
B	3.26 ± 0.49	
C	2.18 ± 0.45	
Human Subjects (N/mm)	**Relaxed (p=0.59)**	**Contracted (p<0.01)**
Sedentary	1.43 ± 0.21	2.05 ± 0.37
Recreational Athlete	1.56 ± 0.22	2.84 ± 0.39
Competitive Athlete	1.71 ± 0.12	3.28 ± 0.14

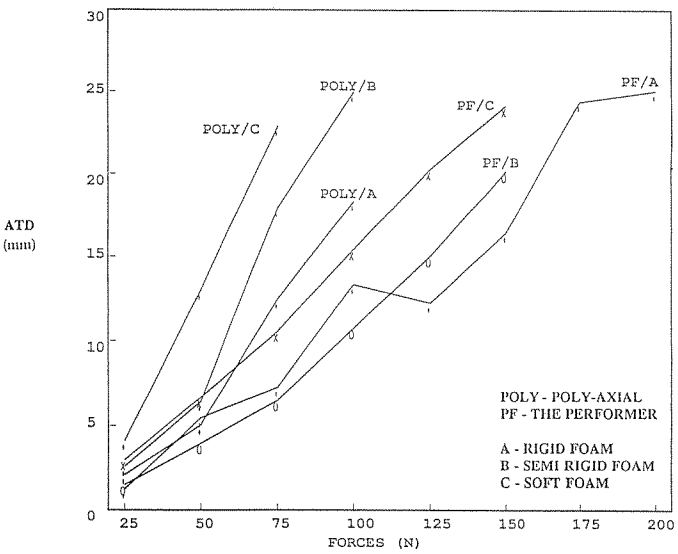

Figure 4.
The role of soft-tissue compliance on functional knee orthosis (Poly-Axial and the Performer) performance.

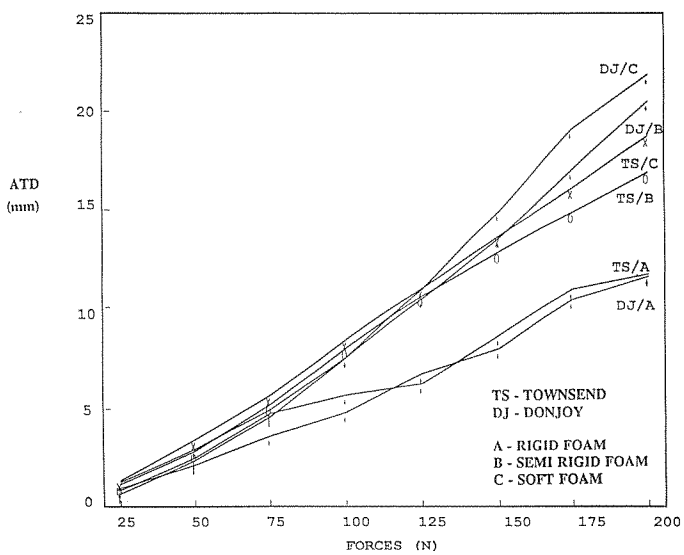

Figure 5.
The role of soft-tissue compliance on functional knee orthosis (Townsend and DonJoy) performance.

compliance at all forces measured. These differences, as seen with the DonJoy orthosis, did not become significant to $p<0.05$ until forces at or above 150 N were applied.

At all forces, the Performer allowed greater ATD than either the DonJoy or the Townsend orthosis. The DonJoy and Townsend orthoses exhibited the best control of ATD and showed no significant statistical difference at both low and high forces. At high forces, with high soft-tissue stiffness, the Townsend orthosis demonstrated the greatest resistance to ATD. The Poly-Axial orthosis, when compared with the other orthoses, reached the 27-mm limit at the lowest force for all soft tissues tested.

DISCUSSION

To our knowledge, no previous studies have investigated the effects of thigh soft-tissue compliance on the control of ATD by custom functional knee orthoses. Reduced ATD was demonstrated by all functional knee orthoses tested. The degree of reduction depended on the compliance of the soft-tissue analog, the type of orthosis, and the force applied.

One major drawback of the surrogate knee used in previous orthosis testing is the lack of quantification of the soft tissue surrounding the knee. The stiffness of each of the soft-tissue analogs used for this study lie within the range of the thigh soft-tissue stiffnesses seen in sedentary, recreational, and well-conditioned athletes. Interestingly, significant differences between the recreational and competitive athletes and sedentary individuals were seen only during quadriceps contraction and not during the relaxed state. It is significant that these differences in thigh soft-tissue compliance exist and depend upon the athletic activity of the individual. These results are especially important today because of the increased use of functional knee orthoses by all segments of the population. As soft-tissue stiffness may indeed be the limiting factor in functional knee orthosis performance (8), this parameter is important in both static bench testing and *in vivo*.

A significant difference in control of ATD was observed when the soft-tissue substitute of the anterior thigh was varied from low to high compliance. Each of the knee orthoses tested demonstrated this dependence on compliance for resistance to ATD. For the Poly-Axial orthosis, the effect of soft-tissue compliance was evident at low forces, but was insignificant when compared to the overall resistance of the orthosis to ATD. On the other hand, for the other three orthoses, varying the soft-tissue compliance affected the resulting ATD, primarily with the application of high forces. Although these three orthoses showed adequate resistance at low forces, the ability to resist ATD was diminished by the effect of soft-tissue com-

pliance when higher forces were applied. In addition, when tested with soft-tissue analogs B or C, none of the orthoses offered enough resistance to limit the amount of displacement to 27 mm with an applied force of over 200 N. Clinical application of this data could indicate that an ACL-deficient knee with bulky and tight thigh musculature (one with less compliance) could facilitate the functional knee orthosis in reducing ATD.

Three of the four orthoses tested in this study (Performer, DonJoy, Townsend) had bilateral hinge-post-shell design that had been shown previously to be the most effective type of orthosis design in restricting ATD (1,5,6). However, these orthoses differ significantly in the degree to which they control ATD. The Poly-Axial orthosis, a unilateral-post-shell design, displayed the greatest amount of ATD at all forces, regardless of the soft-tissue analog. These observations concurred with the results of previous studies (5,6).

ATD is directly related to the force applied. With increased force, all knee orthoses were less effective in controlling ATD. These results correlated with previous studies (1,6,9). Radiographic studies have determined the amount of ATD in subjects with intact ACLs to be 9.8 mm with a range of 5.4–14 mm (10). At low forces, all orthoses were effective in controlling ATD to less than 10 mm. At the highest force applied, 200 N, using the least compliant soft-tissue analog, both the Townsend and the DonJoy orthoses restricted ATD to approximately 10 mm. These observations support the effectiveness of these orthoses in controlling ATD in an ACL-deficient knee at these forces. In addition, the effectiveness of these orthoses depended on the compliance of thigh soft tissue, that is, only low soft-tissue compliance was effective. These observations have not been previously reported.

Because of the tremendous increase in use of functional knee orthoses in patients with ACL deficiencies, as well as those with ACL-reconstructed knees, it is of great importance that the factors of patient physique which affect orthosis efficacy be determined and controlled for as well as possible. The results of this study show that these factors can effect control of ATD by knee orthoses at forces as low as 150 N, forces below those generated during strenuous activities. Thus, in order to employ the functional knee orthosis most effectively, rehabilitation to improve quadriceps strength and bulk will be important not only for older patients with less muscle mass, but also for patients with quadriceps atrophy following surgery as well as for deconditioned athletes. Physicians should consider this information when prescribing a custom functional knee orthosis to an ACL-deficient or an ACL-reconstructed patient who plans to engage in strenuous activity.

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