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Knee Orthoses for Valgus Protection

Experiments on 11 Designs With Related Analyses of Orthosis Length and Rigidity

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Recent years have seen the introduction of a great many knee orthosis designs prescribed for protection against ligamentous injury or reinjury of the knee. The configurations and materials incorporated in these designs vary greatly, but all claim to be very effective. A leg model and 11 different commercially available knee orthoses were tested with static loading to obtain objective data on the relative effectiveness of the 11 designs to protect the knee from externally applied valgus moments. From these data, the effectiveness of each orthosis was calculated in terms of the rigidity contributed to the leg/orthosis combination. At a static valgus loading of 78 Nm, there was an eightfold variation in the rigidities contributed by the various knee orthoses, ranging from a low of 0.9 Nm per degree valgus to a maximum of 7.2 Nm per degree. The authors related analyses of two aspects of knee orthosis design (orthosis length and orthosis rigidity) to effectiveness in protecting against knee valgus overload injuries. Correlations were found between design inadequacies noted theoretically and efficacy problems evident from the laboratory tests. Orthosis length and orthosis rigidity must both be adequate, or the orthosis will not be biomechanically effective.

The past few years have seen the introduction of a large number of knee orthosis designs purporting to have knee-stabilizing capability. While some new introductions contain definite design refinements (*e.g.*, joints with better anatomic tracking, better suspension, or more efficient materials), other new introductions seem inferior. Some designs appear very robust and others frail. The American Academy of Orthopedic Surgeons (AAOS) has recognized the need to give some order and direction for classifying and evaluating the multitude of designs available. In a seminar report on knee braces,[1] the AAOS categorized knee orthoses into three types: (1) prophylactic (intended to prevent or reduce injury); (2) rehabilitative (for use during recovery periods following trauma or surgery); and (3) functional (for long-term use on knees with permanent intrinsic instability). That report called for more efficacy testing of knee orthoses in all three categories.

The intent of this paper is to provide objective data and basic design information so that physicians, therapists, and orthotists are better equipped to make decisions about prophylactic and functional orthotic protection of the medial collateral ligament (MCL). This paper is concerned specifically with MCL protection during sporting activities where the participant may suffer a potentially injurious impact to the lateral aspect of the leg.

Whether using an orthosis to protect a knee from first injury (prophylactic) or reinjury (functional) of the MCL, the requirements for adequate orthotic performance are very similar on the playing field. The authors tested both functional and prophylactic designs.

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FIG. 1. In competitive sports, hypervalgus (medial collateral) injury or reinjury may occur when force is received against the lateral aspect of the knee while it is extended and the foot is in contact with the playing surface.

Knee orthoses must provide protection in dynamic circumstances in real life. Static tests will not tell everything about dynamic performance. However, static tests can tell much about the relative effectiveness of various designs and design variations. A design that performs poorly on a static test is not very likely to fare well on a dynamic test. Paulos *et al.*[5] concluded from experimental evidence that determining static brace characteristics is sufficient for assessing brace mechanical performance on the field.

Sophisticated experimental designs for studying the stabilizing effect of knee orthoses have been described by Baker *et al.*[2] Those designs include force transducers on various ligaments and an electrogoniometer to read varus/valgus angles. The present authors sought to model the situation of valgus force application to the extended knee with the foot fixed in position (Fig. 1). The apparatus for this research consisted of a leg model, a series of knee orthoses, and hardware to impose measured genu valgum moments.

MATERIALS AND METHODS

The leg model was designed to possess minimal intrinsic valgus stability. Skeletal components were fabricated from stainless steel tubing (1.6 cm outside diameter, 0.165 cm wall thickness). Femoral and tibial sections of the tube were joined (1 cm apart) at the knee center by a polyurethane plug. The plug was reduced at either end to match the inside diameter of the tubing. The polyurethane plug was chosen as a coupling between the simulated rigid tibial and femoral sections because it would offer little resistance to valgus angulations (Fig. 2). Medium-density Ethafoam (Dow, Wilmington, Delaware), a polyethylene foam, surrounded the steel tubing. This particular foam was used for construction of the leg model because pressure/indentation tests indicated a durometer approximating that of tensed thigh muscles. The two halves were secured around the tubing with circumferentially wrapped strapping tape (Fig. 3).

Knee orthoses for testing were selected to represent a range of models available that claim to provide valgus support: (1) Lenox Hill (Lenox Hill Brace Shop, Long Island City, New York; (2) NUKO (Camp Therapy Products, Jackson, Michigan); (3) OTI (Orthopedic Technology San Leandro, California); (4) C.Ti. (Innovation Sports, Irvine, California); (5) Lorus (Medical Designs, Azle, Texas); (6) Polyaction 404 (Scott Or-

FIG. 2. Rigid stainless steel femoral and tibial skeletal members of the leg model were joined at the knee center by a polyurethane plug, offering little resistance to valgus angulations.

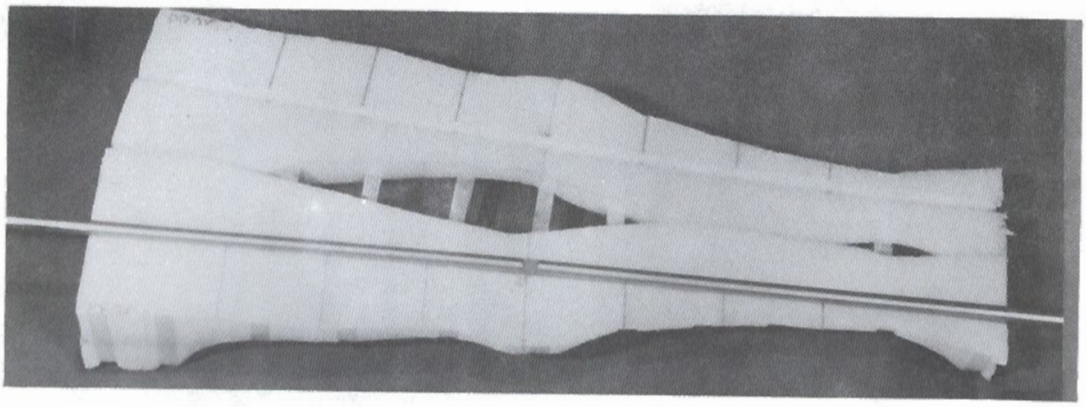
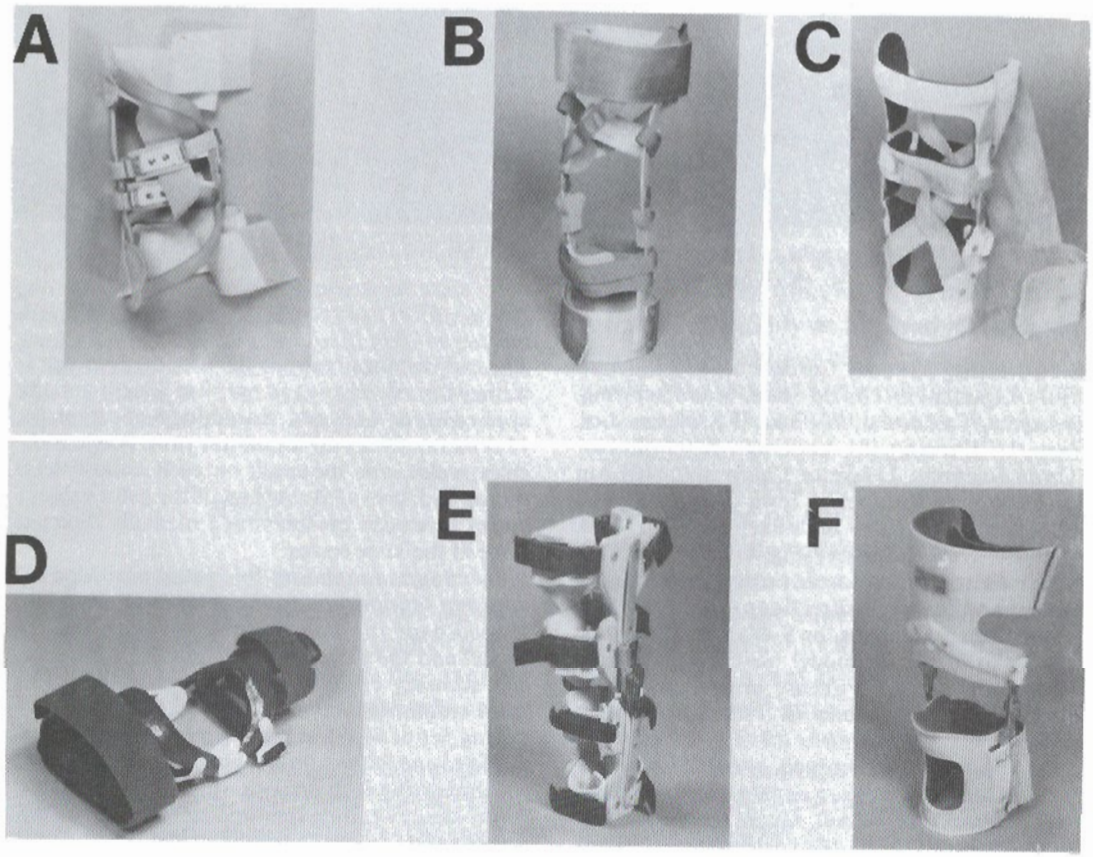
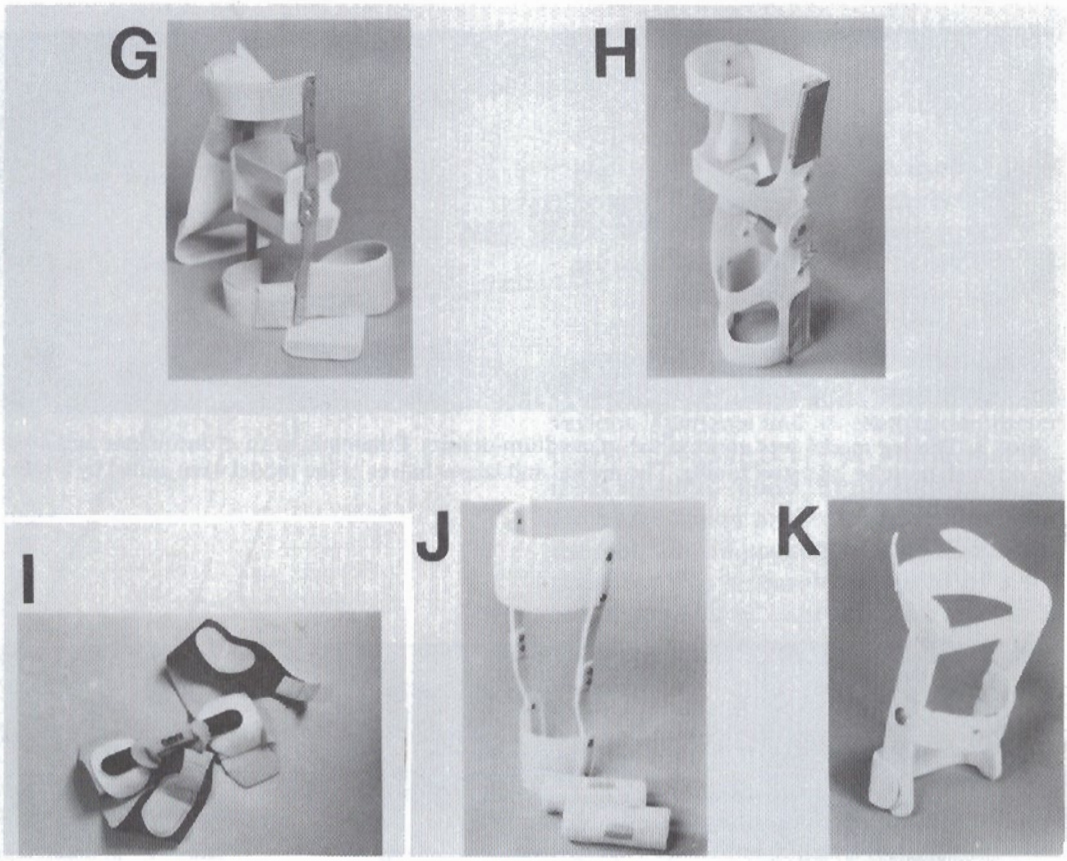


FIG. 3. The leg model was constructed of medium-density Ethafoam, with a durometer similar to tensed thigh muscles, and steel tubing. The medial and lateral halves of the model were joined by binding tightly with fiber tape.



FIGS. 4A–4F. Photographs of knee orthoses. (A) Lenox Hill. (B) NUKO. (C) OTI. (D) C.Ti. (E) Lorus. (F) Polyaction 404.



FIGS. 4G–4K. Photographs of knee orthoses. (G) Lerman Multi-Ligamentus. (H) Ecko II. (I) Anderson Knee Stabler. (J) Am Pro. (K) Three-way Knee-Stabilizer.

thotic Labs, Arvada, Colorado); (7) Lerman Multi-Ligamentus (United States Manufacturing, Pasadena, California); (8) Ecko II (Orthomedics, Brea, California); (9) Anderson Knee Stabler (Omni Scientific, Lafayette, California); (10) Am Pro (American Prosthetics, Iowa City, Iowa); and (11) Three-way Knee Stabilizer (W. J. Teufel, Stuttgart, West Germany) (Fig. 4).

These knee orthoses were ordered according to each manufacturer's directions from leg casts, tracings, measurements, or S–M–L prefabricated choices to fit the leg model used for these tests. When ordering, the purchase order request was specifically for the model or version to protect the MCL.

To impose predetermined, medially directed forces at the knee center, a rectangular framework was constructed of welded, square seamless stainless steel tubing (Fig. 5). Medial support for the leg model was provided by two horizontal bars perpendicular to the leg equidistant from the knee. The half-distance between the support bars determined the effective moment arm length for the applied force and was maintained constant (at 11.5 inches/29.2 cm) for all test runs. Angle indicator scales, one mounted on each endoskeletal tubing end, provided readings of the genu valgum angles produced by applying a medially directed force at the knee center.

The valgus-generating force was produced by applying tension to a webbing strap (5 cm wide) looped over the lateral aspect of both the leg model and the orthosis. Angle reading resolution and accuracy errors were ±0.5°. Load measurement resolution was ±0.23 kg (0.5 lb). For the testing sequence, the orthoses were assigned a randomly generated order. The directions, if any, accompanying each orthosis were read thoroughly before donning, then followed step by step as the orthosis was applied to the leg model. The combination unit (leg model with orthosis) was next mounted on the test frame, and all variables

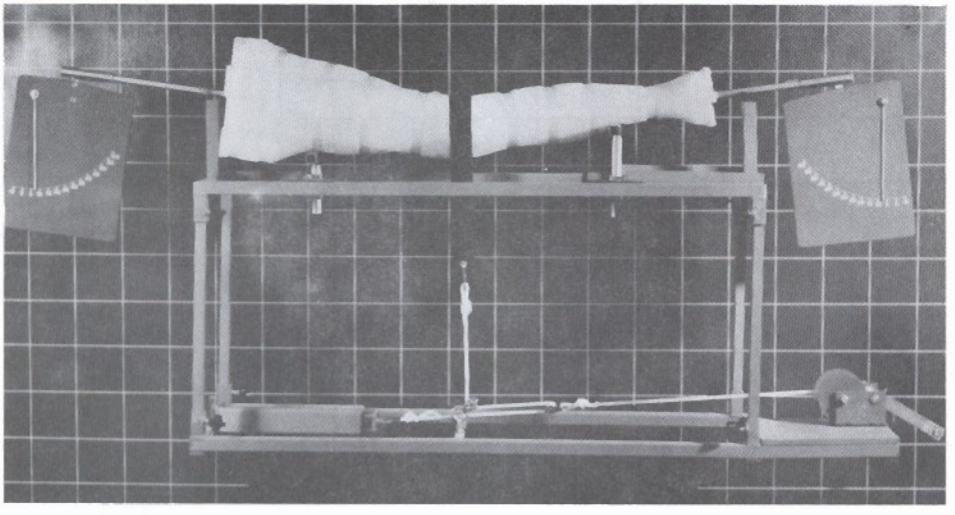


FIG. 5. A rectangular steel framework was constructed to apply valgus moments at the knee center. Force and angulation were measured using a spring scale and two angle finder scales.

were adjusted to consistent specifications before each run.

Force was applied in 4.5-kg (10-lb) increments. Since some evidence of an elastic (time-dependent) deformation was observed, one minute was allowed to elapse before taking readings from the angle scales at each load increment. The genu valgum angle is the sum of the two angle scale readings. Each run terminated at 45 kg (100 lb) or 20° genu valgum, whichever occurred first. Two series of three runs were conducted for each orthosis. The leg model, without orthosis, was test run before and after each series of supported runs.

RESULTS

Figure 6 shows the test data collected (six runs) for one of the knee orthoses. Equivalent data sets were collected for each of the 11 orthoses. For each orthosis, the average valgus angle (from the six runs) was calculated for each load level.

To put these data in a more universal and comparable form, they were converted to units of rigidity. Figure 7 indicates rigidity versus impressed valgus moment for the 11 orthoses. It can be seen from Figure 7, for instance, that at a load of 78 Nm, the unbraced leg (L) demonstrated a rigidity of only 2.8 Nm per degree of valgus, but when supported by the Lenox Hill (Orthosis A), the leg/orthosis combination demonstrated a rigidity of 10 Nm per degree of valgus.

As can be seen from Figure 7, there is some variation of rigidity as the load is increased. The rigidity values corresponding to the lower load levels are probably not very meaningful because that is where the rigidity calculation errors are greatest and because orthosis protection is not needed for very low load levels. The rigidity values become quite consistent at the moderate to higher load levels tested. Because of its inherent valgus instability and the large valgus deformations that resulted under loading, the highest loading at which it was possible to test the unbraced leg model was 27.2 kg (60 lb) force or 78 Nm (57.5 ft-lb) moment. That is also the load level that produced a valgus increase of 8° with even the most rigid leg/orthosis combination (Orthosis A). A valgus increase of approximately 8° will initiate MCL injury (see medial joint opening versus valgus angle

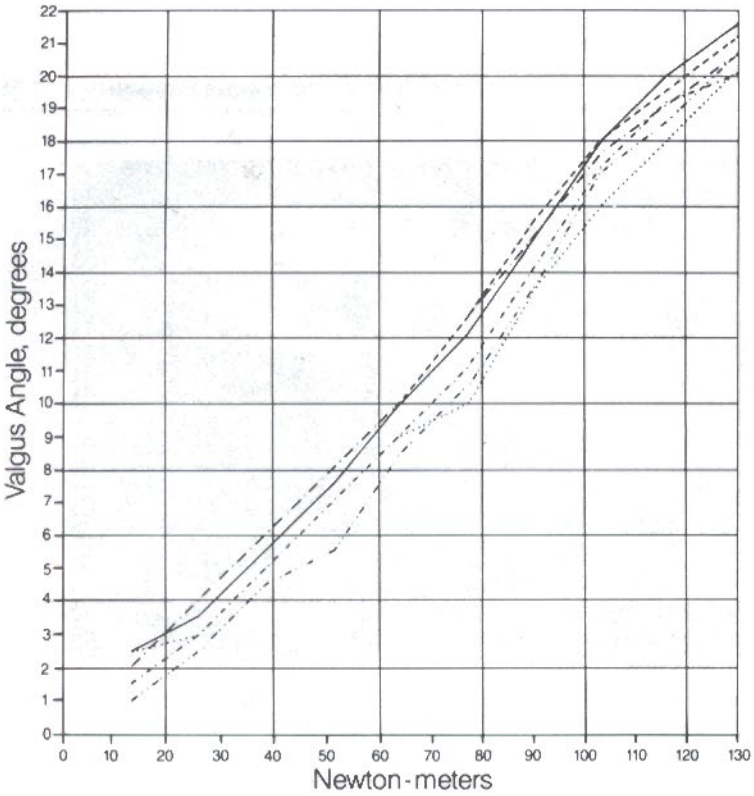


FIG. 6. Data were collected on six test runs for each orthosis. This is a graph of the data collected in the tests of one orthosis (the Polyaction 404). It is a typical example of the data repeatability.

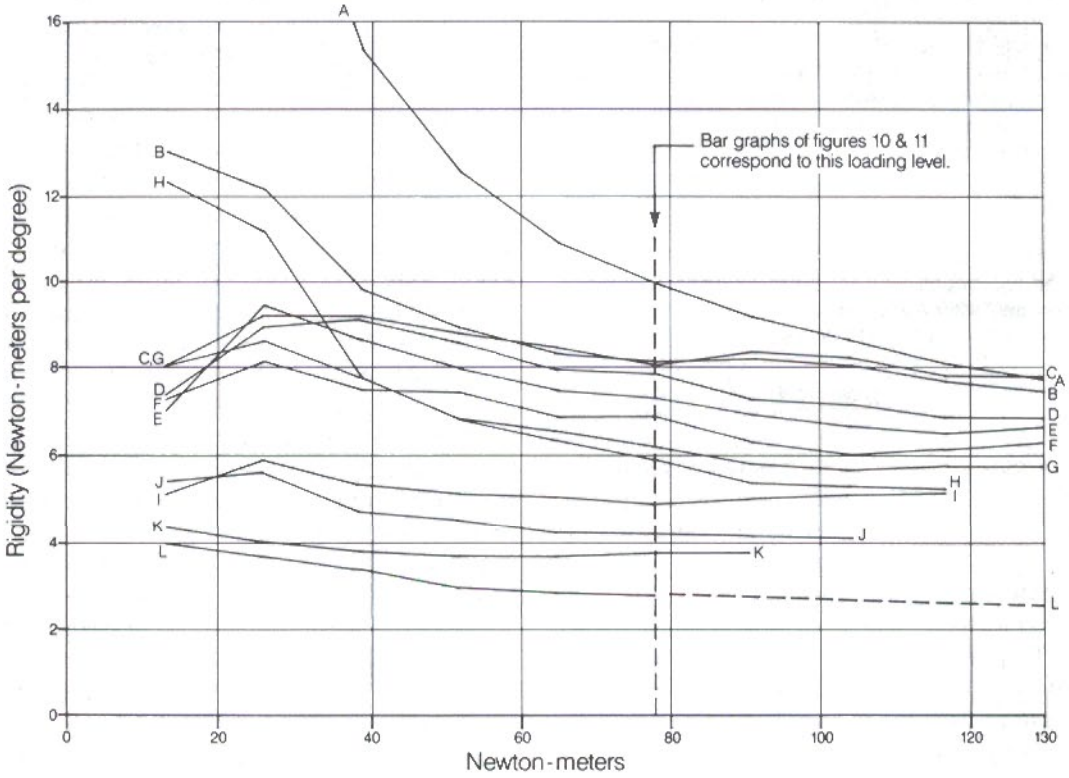


FIG. 7. Average rigidity versus load for each of the 11 leg–orthosis combinations (A–K) and for the leg model only (L). The leg model (without orthosis) rigidity was able to be tested to a maximum loading of 78 Nm. Rigidities of leg–orthosis combinations were compared at that load level.

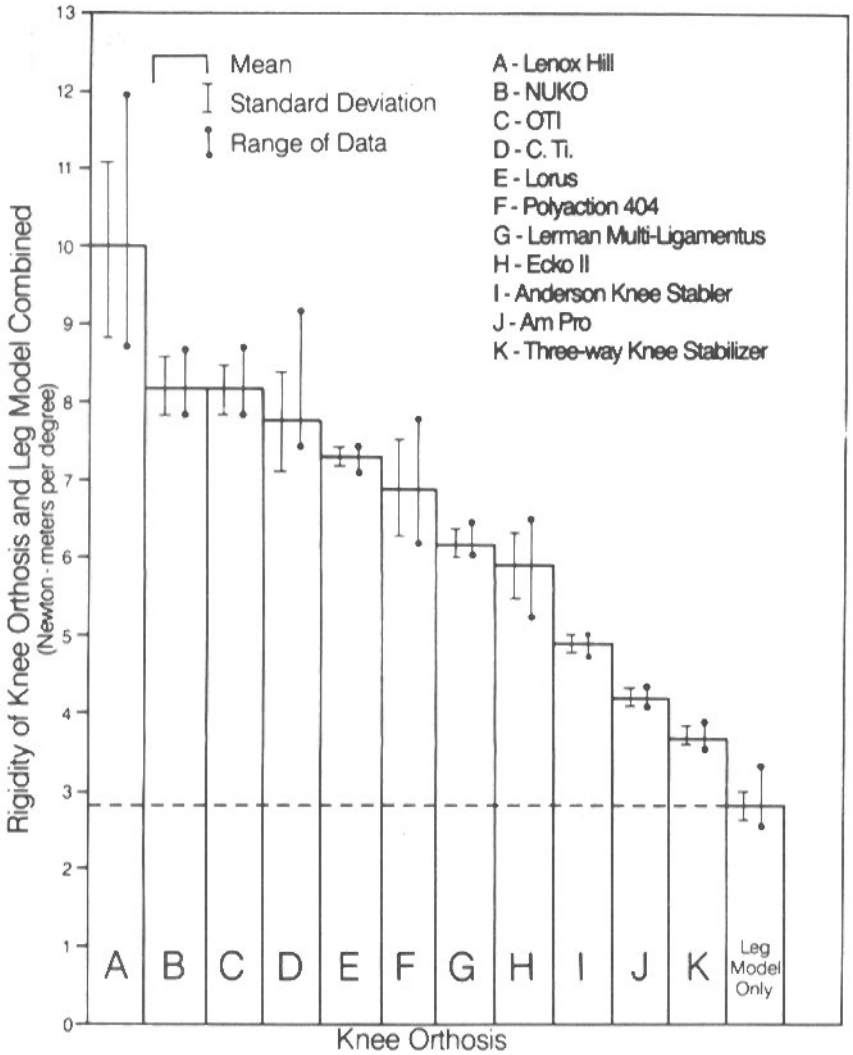


FIG. 8. A comparison of mean rigidity values for each leg–orthosis combination and for the leg model (without orthosis) at 78 Nm loading. The full ranges of the test data and the spans of one standard deviation are indicated.

increase calculations presented later in this paper). Thus, it seems appropriate to compare orthosis rigidities at the 78-Nm load level.

Figure 8 compares the rigidity of each combination, including the value for the unbraced leg model, at the 78 Nm valgus moment. The rigidity of the unbraced leg model was then subtracted from the rigidity of each of the braced combinations to produce the graph for Figure 9. Figure 9 indicates a wide variation among the designs tested.

DISCUSSION

Knee orthoses, as passive devices, develop supportive forces only as a consequence of increasing malalignment of the anatomy they surround. The relationship between the development of malalignment and the devel-

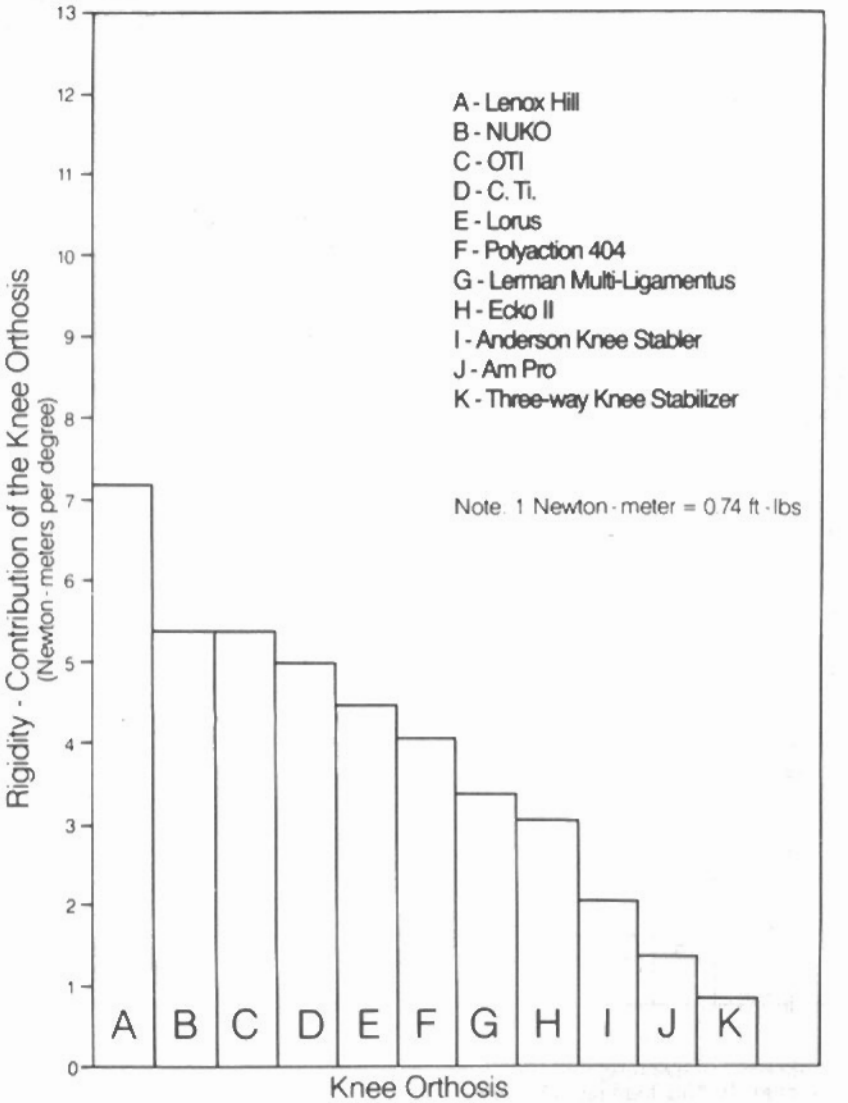


FIG. 9. Subtracting the rigidity of the leg model from the rigidity of each of the leg–orthosis combinations yields the rigidity provided by the orthosis. This bar graph compares the external rigidity provided by each of the 11 knee orthoses at 78 Nm loading.

opment of supportive moments is determined by certain orthosis design variables. The primary design variables bearing on valgus control are orthosis length, orthosis rigidity, and orthosis fit. This discussion is about length and rigidity. Although fit is very important, the authors will leave it as a topic for other papers.

Orthosis length relates to performance in two distinctly separate ways. The first will be mentioned only briefly. By increasing the length of the orthosis, greater effective separation of the stabilizing forces is achieved, yielding longer moment arms. The longer moment arms mean that stabilizing moments may be created with lower forces/

pressures against the anatomy. It is a mechanical advantage factor.

The second way orthosis length relates to valgus control effectiveness is, in engineering terms, the kinematic aspect of the problem and arises from the fact that there are soft tissues lying between the orthosis and the skeleton. This soft-tissue factor is so obvious in a subjective sense that it is easy to pass it off as not worthy of in-depth analysis. However, building precise and thorough knowledge of the kinematic problem does require analysis and is an essential stepping-stone to knowing objectively the relationship between orthosis length and orthosis adequacy.

In the area of the knee joint, medial and lateral skeletal support may be given quite directly because that area has only a thin layer of soft tissue between bone and skin. However, lateral (or medial) support to the tibia/fibula at the midcalf and to the femur at the midthigh depends on first compressing a significant amount of muscle tissue. When potentially injurious valgus forces are applied, the sequence of events is this: (1) The knee valgus angle increases (Fig. 10), and as it does, the midfemur angles outward toward the lateral proximal aspect of the orthosis, compressing the lateral muscle bulk between the femur and the orthosis. An equivalent event occurs simultaneously near the distal end of the orthosis. (2) As the muscle bulk compresses, the orthosis exerts greater and greater supportive forces transmitted through the muscle to the bone. Meanwhile, the supportive forces against the medial aspect of the knee also increase. (3) Knee valgus continues to increase until the supportive forces, when added to the intrinsically developed moments, become great enough to generate a countermoment equal to the externally applied moment.

The point of this detailed sequence description is to illustrate the kinematic part of the problem that must be considered in the moment of potential injury. Figures 11, 12, and 13 illustrate the direct relationship between orthosis length and the effectiveness of

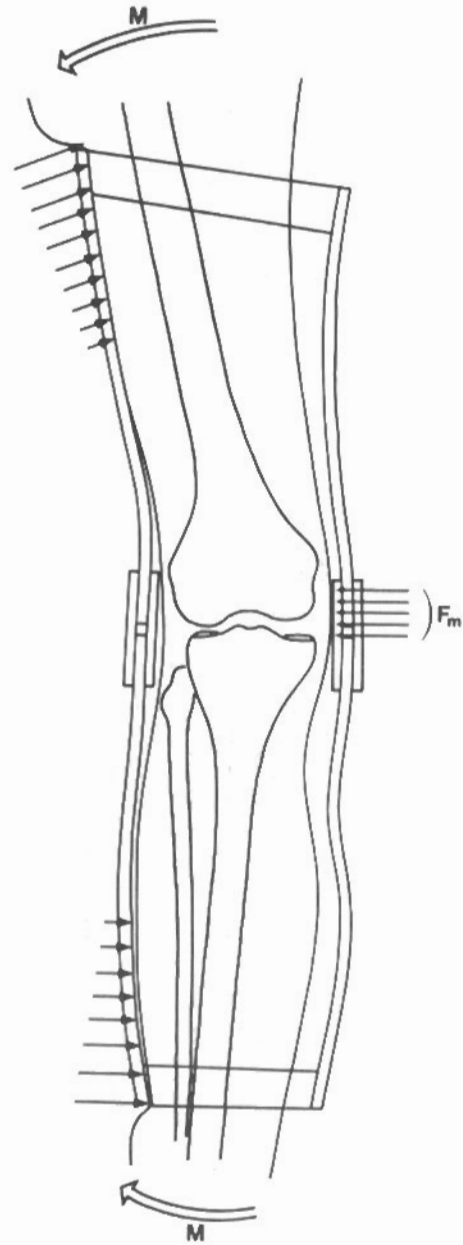


FIG. 10. External valgus forces (applied as in Fig. 1) cause the knee valgus angle to increase. As the skeletal members angle laterally from the knee, muscle bulk compresses and the orthosis exerts increasing supportive forces (indicated by arrows) laterally and against the knee medially (F_m). Knee valgus angulation is stopped when these supportive moments, in addition to intrinsically developed moments, become equal to the externally applied valgus moment (M).

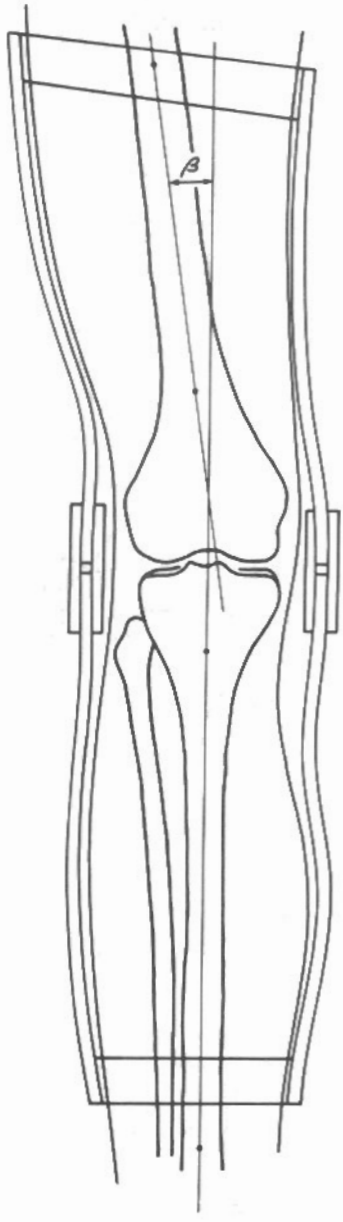


FIG. 11. The natural alignment of the femur and tibia includes a small valgus angle (β).

the orthosis. Figure 11 is a diagram of a leg and orthosis without externally applied valgus forces. The tibia and femur are in a natural undeformed alignment that includes a small knee valgus angle, which shall be symbolized by the Greek letter β. Figure 12 shows the same leg and orthosis under the action of an externally applied valgus moment. Lateral thickness of the muscle bulk at the proximal and distal aspects of the orthosis have been decreased 50% (denoted by the Greek/alpha designations E_{ak} and E_{bk}, respectively). The knee valgus is increased (to $\beta + \Delta\beta_f + \Delta\beta_t$). Figure 13 is a very similar diagram for a knee orthosis that is shorter by 25%. A significantly greater knee valgus angle (about 40% greater) must be generated to produce the same amount of muscle compression and stabilizing force from the orthosis. Also, of course, since the stabilizing forces for the shorter orthosis (Fig. 13) are closer to the knee center, even greater angulation will have to occur (a further degradation of efficacy) before a stabilizing moment is generated equal to that in the case of the longer orthosis of Figure 12. For the purpose of this comparison, both the longer and the shorter orthoses are assumed to be absolutely rigid.

A simple equation relates orthosis length to the valgus angle that length permits. Referring to the notation used in Figures 11, 12, and 13 and using β to symbolize the natural knee valgus angle, if it is assumed that all angle changes are small and designated $\Delta\beta = \Delta\beta_f + \Delta\beta_t$, the trigonometric equation can be written:

$$\tan\Delta\beta = [(E_{ak} \div L_{ak}) + (E_{bk} \div L_{bk})]. \quad \text{(A)}$$

(Equation A is an approximation, accurate to within 2.5% for β values less than 20°.)

For most knee orthoses, the above-knee and below-knee lengths are very nearly equal, so if the total length of the knee orthosis is designated as L_t, $L_{ak} = L_{bk} = 1/2\ L_t$. Then equation A can be simplified to:

$$\tan\Delta\beta = [2(E_{ak} + E_{bk}) \div L_t]. \quad \text{(B)}$$

Equation B can be rewritten:

$$\Delta\beta = \tan^{-1}[2(E_{ak} + E_{bk}) \div L_t]. \quad \text{(C)}$$

The exact values of E_{ak} and E_{bk} will vary depending on the magnitude of external

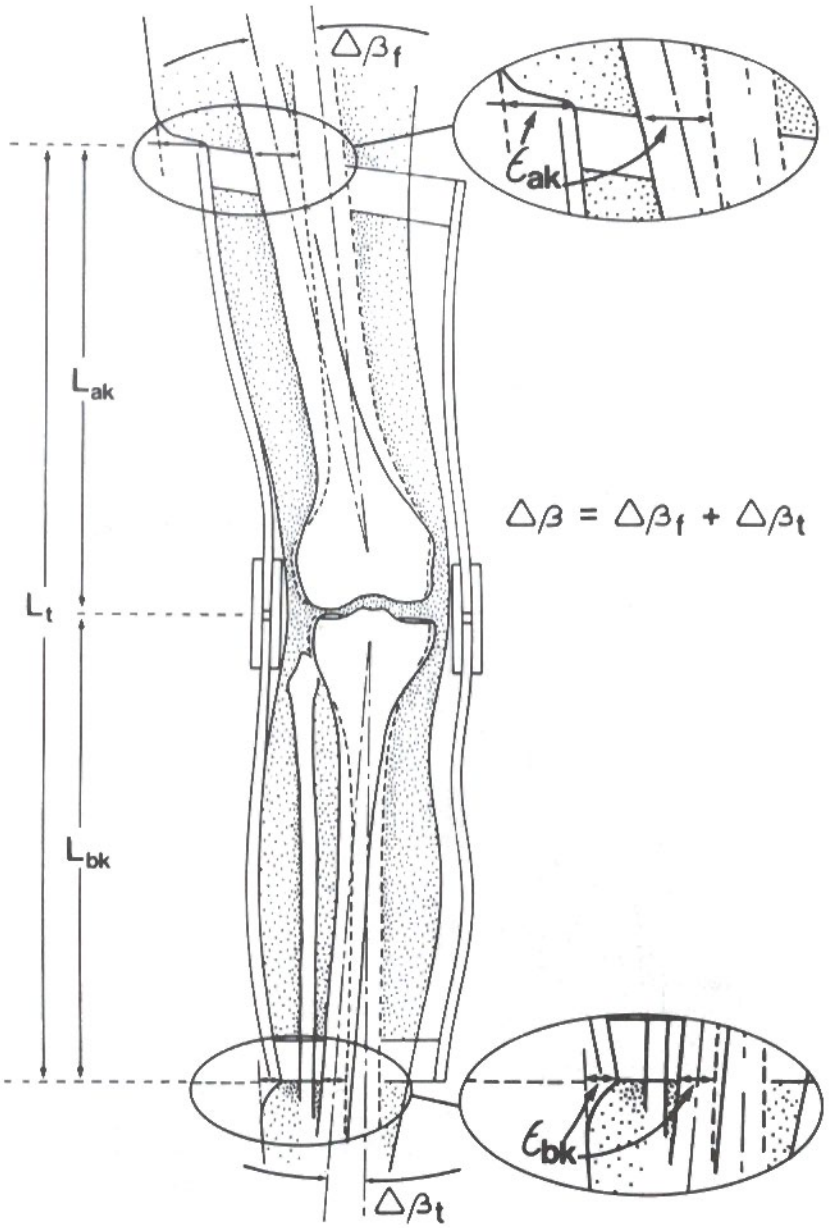


FIG. 12. The leg–orthosis combination of Figure 11 is shown here under the action of an externally applied valgus moment. Lateral muscle bulk thickness has been compressed 50% and the knee valgus angle is increased to $\beta + \Delta\beta_f + \Delta\beta_t$.

force, the compressibility of the muscle, and variations in physical proportions between individuals. The authors, from self-measurement, estimate E_{ak} and E_{bk} to be approximately 1.2 cm and 1.6 cm, respectively. Putting those values into equation C makes it possible to generate a graph (Fig. 14, solid curve) that illustrates the general relationship between the length of the orthosis, L_t, and the knee valgus angle increase, $\Delta\beta$, which is

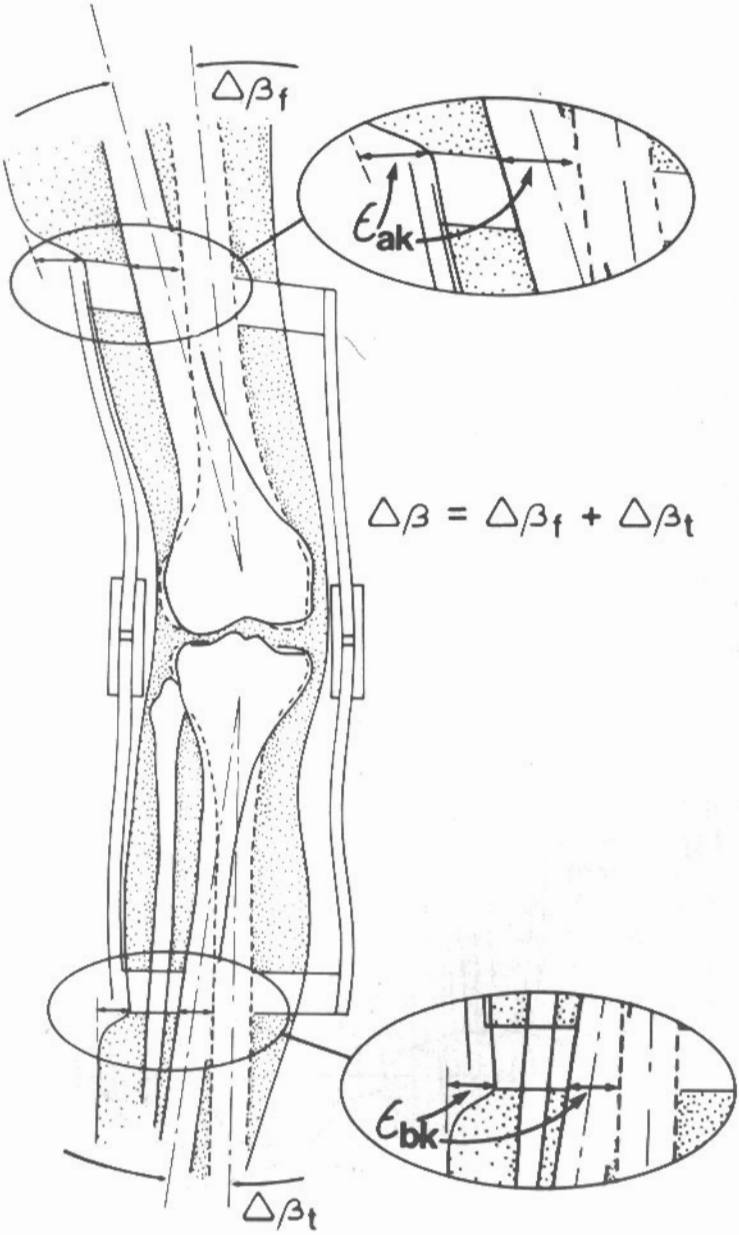


FIG. 13. When the orthosis is shortened 25% (compared to Fig. 12), more knee valgus angulation (40% more) is required to produce the same muscle compression and stabilizing force from the orthosis. Because the orthosis lever arm is now shorter, an even greater knee valgus angle will be required to produce a sufficient stabilizing force.

permitted by an orthosis of that length. If the equation is changed to include 4 mm of soft-tissue compression at the medial knee support, a similar curve is obtained, slightly right-shifted (Fig. 14, dashed curve). Equation C and its graph give quantitative information about the relationship between orthosis length and protection.

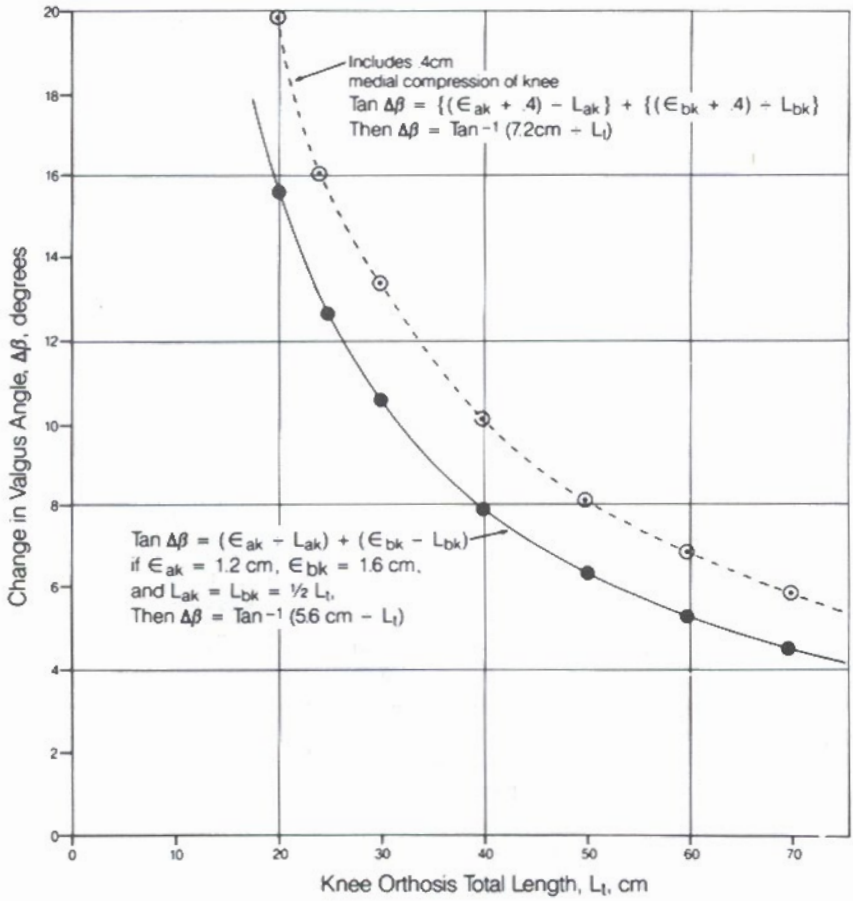


FIG. 14. The hypervalgus angle ($\Delta\beta$) allowed by a knee orthosis is trigonometrically related to the total length of the orthosis. This is a graphic representation of the equation relating hypervalgus angle to orthosis length. The equation represented by the solid line disregards medial tissue compression at the knee. The equation represented by the dashed line assumes 0.4 cm of compression of medial knee tissue against the orthosis at the knee joint line.

A 6-foot man has a leg length of about 100 cm (greater trochanter to lateral malleolus) and can be fit with a knee orthosis at least 55 cm long (one-half the orthosis length above the knee center and one-half below). Lengths of the 11 orthoses tested ranged from 24 cm to 47 cm. The shortest of the lot provided the least protective rigidity. The authors suggest that knee orthosis designers push orthosis length closer to the practical maximum.

At the time of final drafting of this work, papers by Paulos *et al.*[5] and France *et al.*[4] were published. Although that research was specifically related just to lateral knee bracing (rigid orthotic members on the lateral aspect of the leg only), some of their findings were applicable to orthotically generated valgus restraints in general. In particular, the finding[5] that MCL injury began at a medial joint opening of 7 mm and failure was complete at 15–16 mm can be used to give an approximation of knee valgus increases ($\Delta\beta$) necessary to produce MCL injury. Assuming that the femoral knee condyle apices are separated by a distance of 50 mm and the center axis (for hypervalgus motion) lies somewhere

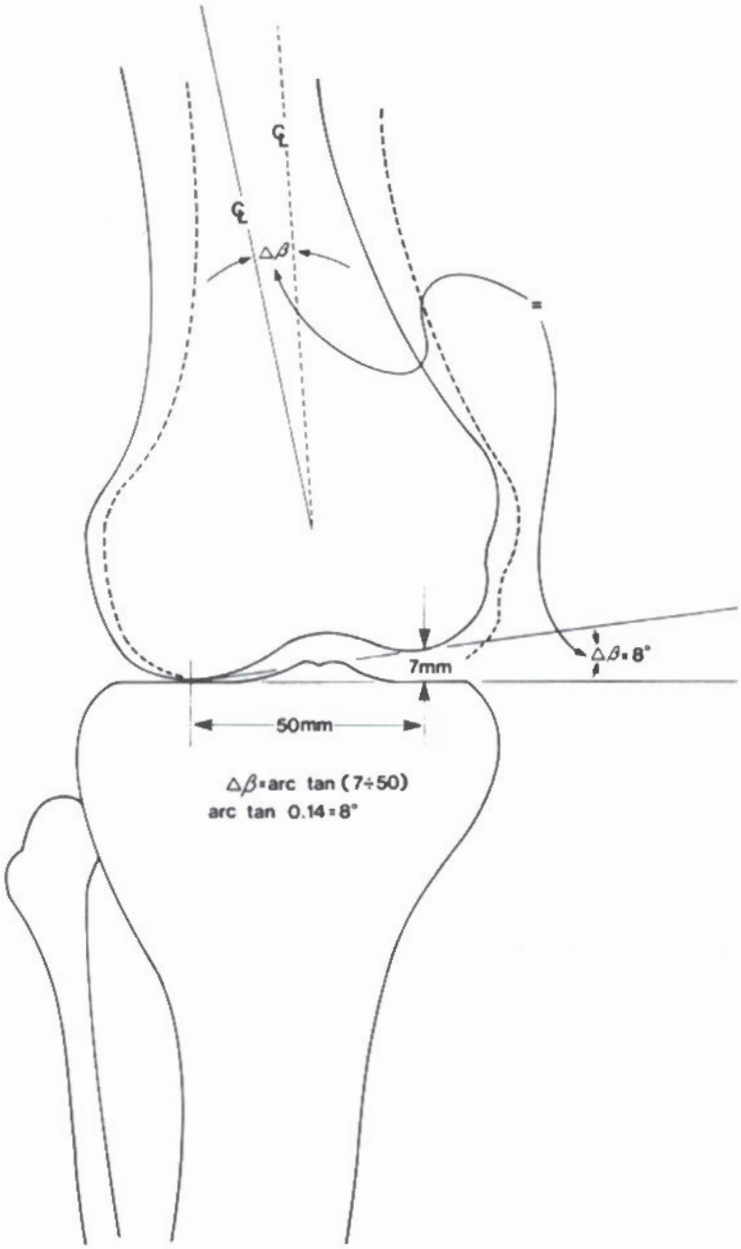


FIG. 15. This diagram shows how to relate medial joint opening to knee valgus increase. Paulos *et al.*[5] found that MCL injury was initiated at a medial joint opening of 7 mm. This corresponds to a knee valgus increase of 8°. If lateral joint compression is known and taken into account, the calculated valgus increase would be somewhat higher.

close to the lateral condyle apex (area of condyle contact), MCL injury is initiated at a knee valgus increase ($\Delta\beta$) of about 8° (Fig. 15) and is complete at about 15°. (If lateral condyle compression amounts are known and taken into account, the $\Delta\beta$ values would be a bit greater.) Relating this approximation to Figure 14 (dashed curve), it can be seen

that if the more conservative figure (8°) is used, a completely rigid, perfectly fitted knee orthosis (giving medial joint line support as well as proximal and distal lateral support) must be at least 50 cm long to be expected to prevent MCL injury. If it is considered that orthoses are neither completely rigid nor perfectly fit, it is probably advisable to examine orthosis length requirements using conservative estimates.

As the reader can appreciate, this length requirement analysis does not yet give precise answers. It presents an engineering method for considering this design parameter. Closer precision will be possible as more is learned about the pertinent physiologic (muscle tissue compressibility/compliance) and trauma onset variables. Further excellent data such as those produced by Paulos *et al.*[5] and France *et al.*[4] and with sophisticated apparatus such as that developed by Youm and Bass[7] will be anxiously awaited. The authors hope future research measurements will give direct evidence of the relationship between knee valgus increase and MCL injury.

In the analysis just completed, the knee orthosis was assumed to be absolutely rigid so that the length parameter could be isolated and evaluated. Now, consider the fact that these orthoses are not absolutely rigid. To the extent that the orthosis is flexible, it will allow even greater valgus angles.

It is not an elementary problem to design a knee orthosis having great rigidity at a moderate weight and monetary cost. There are some guidelines, however, that can be given with fair simplicity: (1) Matching joint component dimensions should be machined to close-fit tolerances and be of wear-resistant materials to avoid the existence and/or development of angular play. (2) Materials should be selected (especially for joint, and side-bar components) that have a relatively high modulus of elasticity. (3) The medial and lateral parts should be well-coupled structurally to each other above and below the knee joint to develop varus/valgus bending resistance. (4) The structural rigidity should be carried all the way to the extremities of the orthosis. An example embodying many of these guidelines may be found in the early version of the Iowa knee orthosis.[6] Butler *et al.*[3] briefly addressed rigidity issues in knee orthosis design. Those authors recognized the need for stiffness in both material and structure.

Among the orthoses ordered and tested were some that the authors knew did not follow one or more of these design guidelines. The Ecko II and Am Pro, for instance, utilize plastic materials with relatively low moduli of elasticity (compared to metals or the best fiber-reinforced plastics) for the joint heads and side bars as well as the cuff shells (Figs. 16 and 17). Both performed as expected during experimental tests (Fig. 9). The Lorus and the Anderson Knee Stabler utilize no rigid structural coupling between the medial and lateral components. In fact, the Anderson Knee Stabler has no rigid medial component. Even the more rigid of these two (the Lorus) exhibited only comparatively moderate valgus support in spite of being the heaviest orthosis of the group tested.

The Polyaction 404 illustrates the importance of the fourth design guideline for rigidity. The benefits of the full length of the orthosis are not realized because the structural rigidity does not extend the full length of the orthosis. The medial and lateral longitudinal bars are very solidly coupled by a crossover bar just above the patella. However, the plastic shell that makes up the thigh cuff is largely left without needed medial and lateral reinforcement above the crossover bar. In fact, there are pieces scalloped out of the shell medially and laterally just above the crossover bar. The structural rigidity of the proximal portion of the thigh cuff is, therefore, significantly sacrificed. The reduced ability of this orthosis to resist angulation of the thigh is clearly seen by comparing the lateral profiles of the orthosis on the leg model in the unloaded (Fig. 18) and loaded (Fig. 19) conditions. The proximal lateral

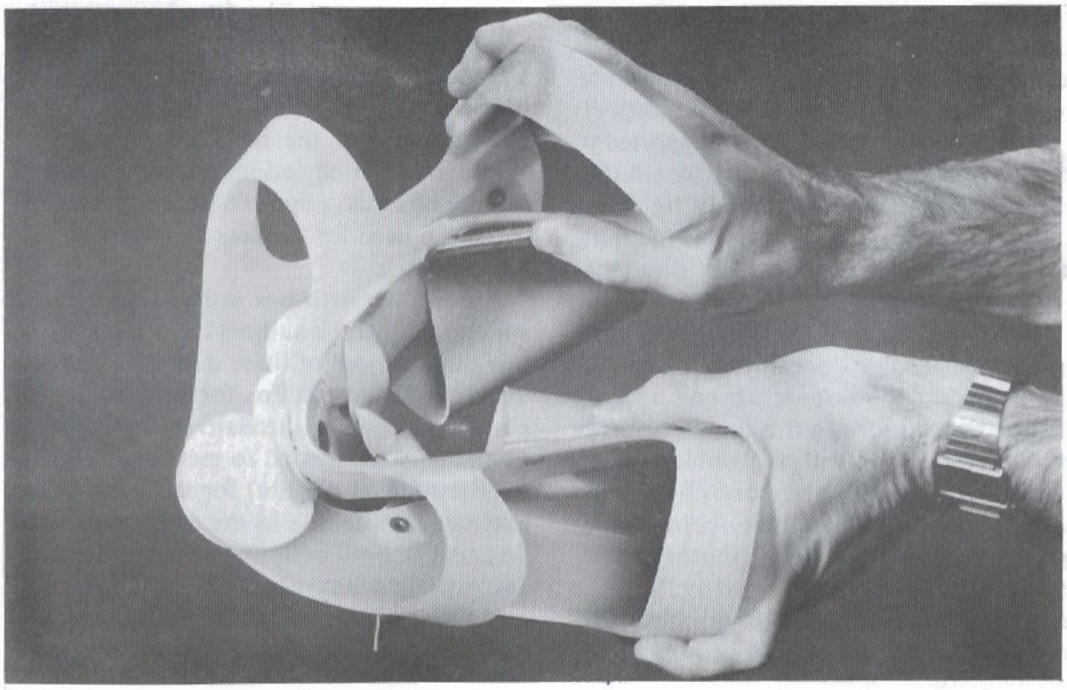
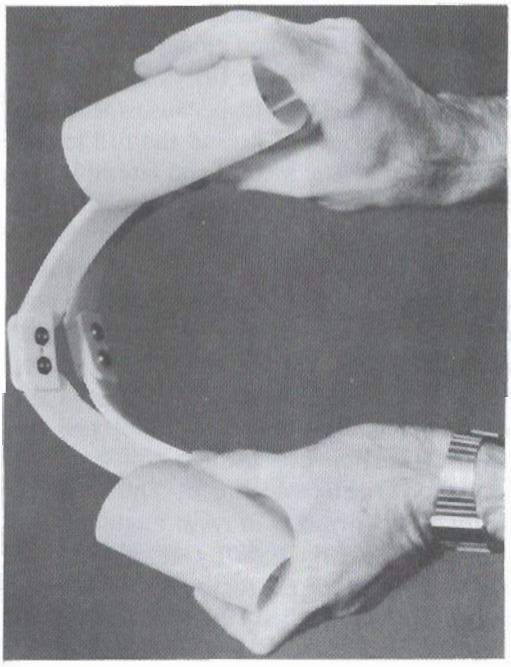


FIG. 16. The Ecko II is constructed of plastics with a relatively low modulus of elasticity (compared to metals or the best fiber-reinforced plastics). This photo illustrates the relatively low structural rigidity of this orthosis.



part of the thigh cuff, which has been freed by the deep scallop, is easily moved laterally by the developing valgus forces (Fig. 19).

In conclusion, the AAOS has issued a position statement on the use of knee orthoses. That position statement calls into question the belief that prophylactic knee braces provide any significant protection to a normal knee during athletic performance known to put the knee at risk. The AAOS position is eminently justified, especially with respect to the short and/or flexible devices normally used for prophylactic bracing. The authors are aware of no research that has established a credible standard of adequate performance for either prophylactic or functional knee orthoses on the playing field or court. The

FIG. 17. The Am Pro is also constructed of plastics with a relatively low modulus of elasticity.

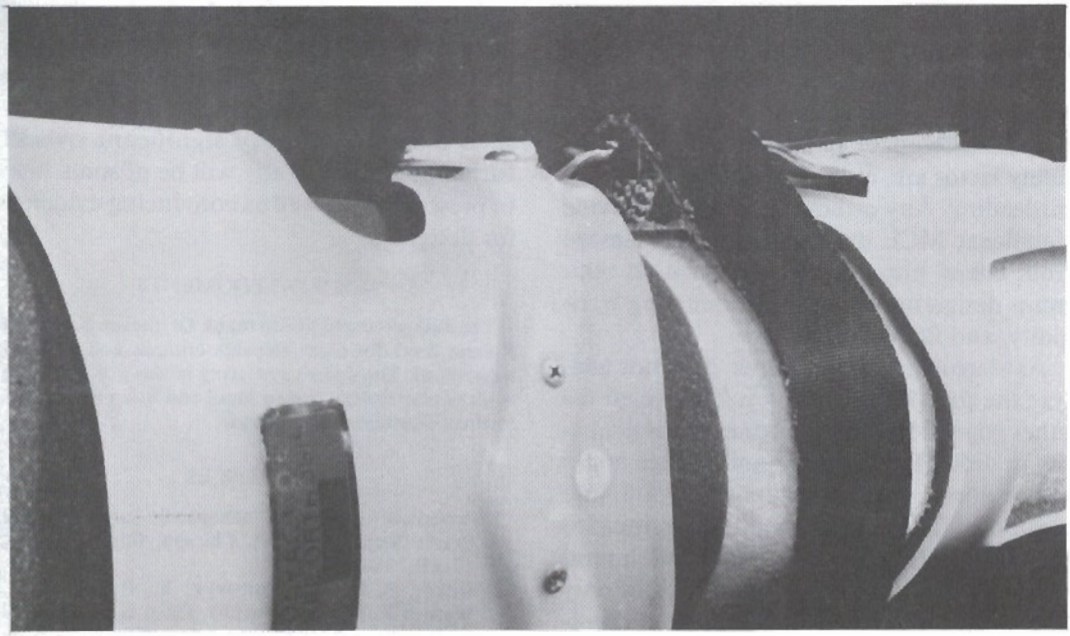


FIG. 18. The Polyaction 404 with no valgus loading applied. Note the lateral alignment of the orthosis on either side of the scallop. The proximal thigh cuff is in good alignment with the side bar.

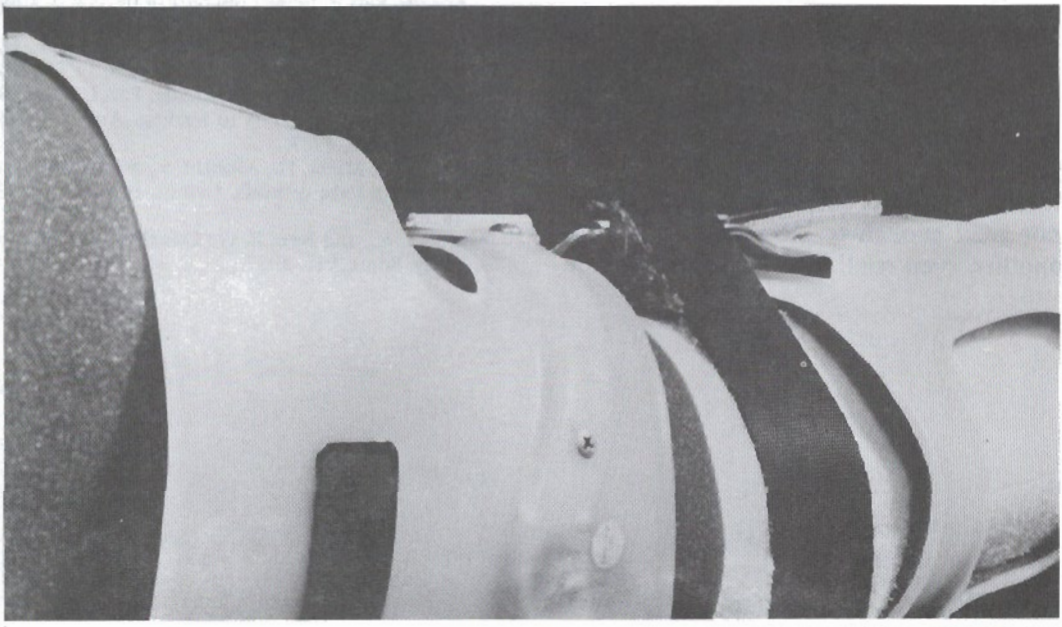


FIG. 19. The Polyaction 404 with valgus loading applied. Note the lateral alignment of the orthosis proximal to the scallop. The proximal thigh cuff is displaced laterally and the knee has assumed a hypervalgus angulation.

forces and moments generated in experiments described here were far below those encountered by athletes, yet seemed to challenge even the best of the functional orthoses tested. References to a safety standard or safety factor are, at this time, premature and misleading. Any orthotic attempt to provide significant MCL protection against damage from lateral impact must approach an optimum design including maximum length, rigidity, and fit.

As stated earlier, this paper does not analyze the role of fit in efficacy. That is left for other papers. However, a comment is probably in order. Paulos *et al.*[5] and France *et al.*[4] wrote about the importance of joint line clearance. The reader should be reminded that those papers only considered lateral knee bracing (knee braces comprised of only lateral rigid structural components). Therefore, those authors' caution referred to the need for lateral joint line clearance. For a knee orthosis with both lateral and medial structural components, medial joint line clearance should be minimal for best MCL protection.

The reader is cautioned to keep in mind that there are performance factors other than those tested and commented on in this work. Figure 9 should not be regarded as a comprehensive ranking of effectiveness. The differences between some of the orthoses are not great enough to judge one better than another, even relative to the specific investigation. For instance, the standard deviations in the test data for NUKO, OTI, and C.Ti. are greater than the differences between each of their average rigidities. However, the results document a very significant overall variation that hopefully will be of some help to prescribers, as well as convincing evidence for designers.

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