INTRODUCTION

Motion of the knee joint is much more complex than flexion about a simple hinge or fixed axis of rotation. Varying amounts of displacement, internal-external rotation, and abduction-adduction may accompany flexion-extension. Knee motion may be visualized as the rotation of the femur about a series of three-dimensional instantaneous axes rather than a single fixed axis. Knee motion with proper joint stability is a result of the complex interaction of the ligamentous and capsular structure surrounding the joint, the geometry of the opposing articular surfaces, and the musculo-tendinous activity across the joint. The path or locus of the continuously moving instantaneous axis will vary with the activity being performed, the amount of inherent laxity in an individual’s knee, variations in how individuals perform similar functional activities, and whether or not joint instability exists due to ligamentous or capsular insufficiency.

Motions intrinsic to orthotic knee joint designs are much less complex than corresponding natural knee motion. In most cases, orthotic flexion occurs about a fixed axis of rotation as allowed by simple hinges, or about a single pattern of axes (polycentric) prescribed by a variety of mechanisms such as the interaction of two cam surfaces, two geared surfaces, or on a roller in a slot design. Note that the polycentric designs just mentioned are still more simplified than natural knee motion because such joint mechanisms provide one single locus of axes for all possible functional conditions, whereas the locus of instantaneous axes of the knee varies with different functional conditions.

An orthosis should hypothetically allow a full, unrestricted range of normal joint motion to occur except at appropriate limits of motion where orthotic constraints are intentionally introduced to provide extra stability required to compensate for soft tissue insufficiency. When an orthosis is applied to the knee, however, a conflict occurs as the orthosis attempts to force the knee to follow its simplified motions. Since this is prevented by natural joint structure (ligaments, muscles, articular...
surfaces), unwanted constraint forces are also generated in the orthosis at suspension points causing the interface components to migrate or piston over the limb segments during the supposed unrestricted range of normal motion (usually flexion-extension). Note again that some orthotic constraints are beneficial when they compensate for lacking stability (such as medial-lateral force for correction of varus or valgus), yet those which arise from conflict of joint motions are detrimental when they occur during unaffected normal phases of knee motion. Clinical consequences of these unwanted, over-constraint pistoning forces are a possible obstructed range of normal motion, or discomfort due to skin irritation from increased pressure over bony prominences at suspension points.

Many orthotic designs, some of which have been mentioned above, have evolved in an attempt to minimize the constraint forces and migration effects. However, no objective evaluation has been undertaken to demonstrate the relative efficacy of these designs.

**OBJECTIVE**

The objective of this study was to develop an experimental method to quantitatively evaluate the relative efficiency of knee orthosis joint designs. The comparison was based upon the tendency of the orthotic joints to cause migration or pistoning during motion. The pistoning tendency was quantified by designing a transducer which measured the portion of the orthotic constraint force which was directed parallel to the sidebars which attach the joints to the orthotic interface components. The tests were performed on a human subject with normal knee laxity. The rationale for this is that since no soft tissue instability exists in the subject, any constraint forces that occur will reflect only the conflict between the simple orthotic and more complex anatomical knee motions, thus an indication of the migration tendency and efficacy of the orthotic knee joint designs.

**METHODS AND MATERIALS**

Interface components were fabricated for the human subject. Orthotic knee joint designs, including several commercially available types, as well as a design from our laboratory, could be interchangeably attached to the interface components. The pistoning force transducers, which were developed for this study, were installed on both the medial and lateral orthotic joint sidebars, just proximal to the joint. Pistoning constraint forces were then experimentally measured for each joint design as the subject performed a series of functional activities.

![Commercially available orthotic joints tested: posterior offset (left), single axis (middle), polycentric with geared articulating surfaces (right).](image)

**Description of Orthotic Joints**

The three commercially available joint designs tested were 1) the single axis hinge, 2) the posterior offset hinge, and 3) the polycentric hinge (Fig. 1). The polycentric design provides motion about a single path of axes as prescribed by two geared surfaces which are mechanically constrained. The posterior offset design is based upon a single axis approximating the location of the sagittal radius of curvature of the posterior femoral conyles, which articulates with the tibia in flexion.

The orthotic knee joint designed in our laboratory can be referred to as the "optimal single axis" joint. "Optimal single axis" refers to the optimal location and orientation of a single axis of rotation for a range of motion such that flexion about...
Figure 2—Position of single axis hinges defining the "optimal single axis of rotation" for extension to 90° flexion, were predicted to be posterior and distal to the traditional placement of single axis hinges.

Figure 3—Resultant longitudinal pistoning force (left) is the vector sum of the medial and lateral sidebar forces measured by the pistoning transducers (either tension or compression), and causes the pistoning or migration of the interface (right).
this single axis most closely approximates the equivalent complex anatomical motion. Thus, this "new" design is actually a method which predicts the optimal placement of single axis hinges. The formulation of this optimal single axis is based upon a mathematical model of the knee\(^7\), and can be conveniently custom incorporated into the fabrication technique for individual orthotic devices for particular ranges of motion, if desired. Details of the optimal single axis procedures will not be described in this report since it is not the major objective of this study. The average of this data will be used to locate the optimal single axis on the human subject in this study (Fig. 2). When compared with the traditional placement of single axis hinges on an orthotic interface (bisect distance between adductor tubercle and medial joint space; bisect distance between patella and popliteal region) the average optimal single axis for the six subjects was found to be

- **medial side of knee**: 21 millimeters posterior 0 millimeters proximal-distal
- **lateral side of knee**: 26 millimeters posterior 9 millimeters distal

This asymmetrical axis was located in the study by contouring single axis hinges at the appropriate locations just described.

**Description of Pistoning Force Transducer**

Migration or pistoning clinically manifests itself as the longitudinal "riding up and down" of the orthotic components over the lower limb segments. An orthotic constraint force is potentially three-dimensional in nature; that is, it can have components in the longitudinal (superior-inferior), anterior-posterior, and medial-lateral directions (Fig. 3). Constraint forces in the anterior-posterior and medial-lateral directions, along with the movements which they create (sagittal, transverse, and torsional), are predominantly present at times when the orthosis provides useful compensation for soft tissue instability. Constraint forces in the longitudinal direction, on the other hand, primarily lead to the unwanted pistoning of interface components during normal phases of motion. Constraints in the other directions are probably present but insignificant in this case. Measurement of longitudinal sidebar constraint forces, and their subsequent vector addition (taking into account whether they act in tension or compression), quantifies the resultant pistoning constraint force acting at the orthotic interface (Fig. 3), which gives rise to component migration.

A transducer was designed (Fig. 4) which 1) measures the longitudinal pistoning constraint force in each sidebar (and differentiates between tension and compression), 2) is insensitive to moments created by extraneous components of the constraint force, 3) is unobtrusive during functional activities, and 4) can be interchangeably attached to orthotic sidebars.

The lightweight aluminum transducers (Fig. 4) were approximately 3½ inches long, with a reduced cross section in the middle portion, and two recesses (one on each end) used to securely clamp the transducer to the orthotic sidebars. Four semiconductor strain gauges were installed on each transducer, two in the transverse plane and two in the sagittal plane of the reduced cross section. The gauges were placed at the bottom of the notches (Fig. 4 and 5) so that they would be as close as possible to the neutral axis in each cross section, thus minimizing the effects of orthotic constraint components other than the longitudinal pistoning force (torsional, sagittal and transverse bending moments, if present at all).

To further cancel out these extraneous effects and to ensure that migration comparisons are based solely upon the longitudinal portion of the pistoning constraint, one strain gauge from each cross section was placed in series, and formed opposite arms of the Wheatstone bridge circuit (Fig. 6), amplifying the longitudinal strain approximately four times, and cancelling out the response due to out-of-plane movements.

The lead wires from the strain gauges (and the cable containing these wires) were stress relieved (Fig. 4 and 6) in sev-
eral places, so that tension on the cable during testing would not harm the gauges. The gauges were also protected and waterproofed by several layers of gauge coat (Fig. 4). The strain gauges and Wheatstone bridge were connected to a Beckman strip chart recorder.

The pistoning transducers could be installed on both medial and lateral sidebars, could be easily interchanged among the joint designs tested, and their presence on the evaluation orthosis was unobtrusive and did not inhibit normal knee motion in any way. The transducers were installed as follows (Fig. 6). A 1½ inch section of each sidebar was removed just proximal to the joint mechanism. The recesses on both ends of the transducer (Fig. 4) were designed to securely accommodate the remaining ends of the sidebar, so that the transducer takes the place of the sidebar section removed (Fig. 7). The neutral axes of the reduced transducer cross section were in direct line with the neutral axes of the orthotic sidebars, thus preventing moments inherent in the system. The top of the clamps were screwed down so that
the sidebars did not move within the recesses. Each sidebar was prepared in an equivalent manner, so that the transducers could be interchangeable among the joint designs.

The pistoning force transducers were directly force calibrated before and after each test procedure, so that the voltage output of the strain gauges could be related to an equivalent amount of force (newtons/millivolt). The calibrations were performed by hanging a series of weights from a calibration bar secured to one end of the transducer. During the test procedure, a zero force baseline was determined, so that tension or compression in the transducers indicates whether the longitudinal sidebar forces were directed distally or proximally. A series of bench tests were also performed prior to testing, to demonstrate that the pistoning transducers do cancel out extraneous constraint forces and movements, so that pistoning comparisons will be valid.

**EXPERIMENTAL PROCEDURE**

The evaluation orthosis (Fig. 7) was fabricated as follows. A plaster impression was taken of the right lower limb of one human subject. The positive plaster impression was modified, with emphasis given to the parallel buildups on both sides of the knee to ensure that orthotic joints were parallel. Sidebars containing the orthotic joint designs were contoured to the positive plaster impression, so that hinges were located as previously described. Proximal and distal orthotic interface components were fabricated by vacuum-forming high density polyethylene over the positive plaster impression. The interface components were adequately suspended proximally in the medial femoral area, distally at the medial tibial flair, and circumferentially in the thigh and calf region by broad straps composed of gum rubber with a leather backing. The interface components were capable of accepting interchangeable joint designs with accompanying sidebars.

An initial force calibration of the pistoning transducers was performed, and then the transducers were installed on the medial and lateral sidebars of one of the orthotic joint designs (Fig. 6). The joints and sidebars were attached to the appropriate locations on the interface components, and the evaluation orthosis was applied to the knee of the subject (Fig. 7). The medial and lateral longitudinal pistoning constraint forces were recorded during the following activities (refer to Fig. 8A-E):

1. **Unloaded Flexion**—non-weight bearing flexion-extension (and hyperextension), with forces recorded at flexion angles indicated on Fig. 8a;
2. **Loaded Flexion**—repeating the flexion-extension range in (1), with the addition of the weight bearing condition (partial deep knee bends);
3. **In/Out of Chair**—beginning in a standing position, the subject sat in a chair, then got out of the chair—this activity was repeated twice (Fig. 8D);
4. **Level Walking**—forces were measured from heel strike to heel strike of the limb containing the evaluation or-
Figure 8—Mean and standard deviation (newtons) of absolute magnitude of resultant pistoning forces for 15 repeated applications of the test orthosis to the subject's lower limb during the following functional activities: (A) unload flexion, (B) level walking, (C) up/down steps, (D) in/out chair, (E) loaded flexion.

thosis, during two consecutive gait cycles (note that this motion contains both stance and swing phases of gait); (5) Up/Down Steps—beginning in a standing position on the floor, the subject stepped up on a 16 inch height, then returned to the floor, leading with the evaluation orthosis limb in both cases—this maneuver was repeated twice (Fig. 8C).

Note that flexion angles in (1) and (2) above were measured by a simple handheld goniometer. The evaluation orthosis was then removed from the subject's limb, and placed on a laboratory bench so that a zero force baseline could be recorded for the isolated, unloaded state of the transducer-sidebar complex. After several minutes, the evaluation orthosis was reapplied to the limb of the subject, and the above test sequence repeated. Pistoning constraint force data was recorded for a total of fifteen orthosis applications for each joint design, the purpose being to estimate the portion of the constraint force due to the variations in interface component fit among repeated applications of the orthosis by the same subject. Once known, this error can be averaged out, leaving only the pistoning constraint force due to the
particular joint design. After testing of one of the four joint designs, both transducers were again removed and force calibrated, with the calibration constants (newtons/millivolt) being taken as the mean of the individual pre- and post-test calibration trials. The entire test procedure above was repeated for each of the orthotic joint designs; polycentric hinges, and single optimal axis hinges.

RESULTS

A typical set of data is demonstrated in Fig. 8 summarizing the pistoning constraint forces for a particular joint design, this one being for the polycentric hinge. The standard deviations in the figure indicate the scatter in forces due to the reapplication of the evaluation orthosis fifteen times, as previously described. The force values in Fig. 8 are all positive as they represent the absolute value of the magnitude of the result longitudinal pistoning force. Note that with unloaded and loaded flexion in Fig. 8A, E, force levels were recorded at particular flexion angles. In the remaining three functional activities (Fig. 8B, C, D), the observer recorded only the "end points" of the activity, such as "stand-sit" for getting in and out of a chair. For a particular activity, however, the resultant pistoning outputs for all four joint designs were equivalently shaped, indicating that certain physiologic conditions repeatedly occurred during the activity, such as the shift in body weight or the tension in muscular groups. Since no electromyographic or photographic record of the activities were obtained, the activities were not defined in more detail than the end points. When reducing the data, however, forces representing some of the obvious equivalent, un-named physiologic conditions were included. They are indicated by the force values other than the end points defined in Fig. 8B, C, D).

For the purpose of comparing the four orthotic knee joint designs, the data as typified in Fig. 8 was further reduced to the means and standard deviations of all the recorded resultant pistoning constraint forces for each activity, for each joint design, as presented in Figs. 9-13. For each of the functional activities, these mean resultant pistoning forces were normalized over the four joint designs, as indicated by the bar graphs at the top of Fig. 9-13. The tables at the bottom of Figs. 9-13 present the statistical significance of the difference between the means (and standard deviations) of the resultant pistoning forces for each of the joint designs, during the particular activity. This significance is based upon the calculation of standard or Z scores. To compare two joint designs, follow the respective row and column to the appropriate square. NS indicates that there is no statistical significance between the resultant pistoning forces generated by the two orthotic joint designs during the

Figure 9—Single axis and polycentric hinges produce statistically significant lower pistoning forces than the posterior offset and optimal designs, during unloaded flexion.
Figure 10—Single axis hinges give rise to the lowest mean pistoning forces during flexion, but the difference between the four joint designs is not statistically significant.

Figure 11—Optimal single axis hinges produce the lowest mean pistoning forces during level walking (statistically significant at p < 0.01), followed by the posterior offset and polycentric hinges.

Figure 12—Posterior offset hinges generate the lowest mean pistoning forces with getting in/out chair, but the difference between the four joint designs is not statistically significant.

Figure 13—Optimal single axis hinges cause the lowest mean pistoning forces during up/down steps, however, the difference between four joint designs is not statistically significant.
particular activity. When $p \pm 0.01$ appears, a one percent level of significance exists; that is, there is a probability of 0.99 that the pistoning forces produced by two joint designs are significantly different (in 99 out of 100 cases), or a probability of 0.01 that they are not different ($p \pm 0.01$). A $\pm 0.05$ indicates a 5 percent level of significance. An overall comparison of the four joint designs with respect to the above parameters, based upon the combination of forces for all five activities, is presented in Fig. 14.

Fig. 9 demonstrates that the single axis and polycentric hinges produce statistically significant lower pistoning constraint forces than the posterior offset and optimal designs during unloaded flexion.

The data in Fig. 10 indicates that single axis hinges give rise to the lowest mean resultant pistoning forces during loaded flexion, however, the difference between the four joint designs is not statistically significant.

Optimal single axis hinges (Fig. 11) produce the lowest mean pistoning forces during level walking (significantly different than the others designs at the one percent level), followed by the posterior offset and polycentric hinges.

Fig. 12 shows that posterior offset hinges generate the lowest mean pistoning constraint forces with getting in/out of a chair, however, the difference between the four joint designs is not statistically significant.

Optimal single axis hinges (Fig. 13) cause the lowest mean pistoning forces during up/down steps, but again, the difference between the four designs is not statistically significant.

When resultant pistoning forces are combined for all five functional activities (Fig. 14), the optimal single axis hinges generate the lowest mean pistoning forces, followed by the polycentric and posterior offset designs, although there is no statistically significant difference between the three.

DISCUSSION

Several interesting observations are evident from the data. First, there are differences between the resultant mean pistoning constraint forces due to the orthotic joint designs in each of the activities tested. However, no one orthotic joint consistently generated lower pistoning forces in all of the activities. Also, in most cases, the differences in mean pistoning forces that do exist between joint designs are not significant. For example, when resultant pistoning constraint forces were combined for all the activities tested (Fig. 14), the optimal single axis hinges produce the lowest mean pistoning force, followed in order by the polycentric and posterior offset designs. However, there is no statistically significant difference between the pistoning forces due to these three orthotic joints. This implies that based upon the criterion of pistoning tendency, no one of these three orthotic knee joint designs offers an advantage over the others.

For most of the functional activities tested, there was greater variation in the

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\text{COMBINED RESULTS FOR ALL ACTIVITIES}
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<td>Posterior</td>
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<tr>
<td>Polycentric</td>
<td>22.5(16.8)</td>
<td>20.6(16.1)</td>
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<td>Optimal</td>
<td>18.6(16.9)</td>
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Mean (standard deviation) of pistoning forces during all activities—newtons

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Statistical significance of difference between mean pistoning forces; NS not significantly different

Figure 14—When force results are combined for all five functional activities, the optimal single axis hinges generate the lowest mean pistoning forces, followed by the polycentric and posterior offset designs, although there is no statistically significant difference between the three.
pistoning constraint forces due to the fifteen reapplications of the orthosis with a particular joint design, than there was between the pistoning forces due to the four orthotic joints during a specific activity. This is particularly evident from force results during loaded flexion (Fig. 10), getting in/out of a chair (Fig. 12), and climbing up/down steps (Fig. 13). This implies that for many functional activities, it does not matter which of the four orthotic joint designs tested are incorporated into an orthosis, since any advantage of one over another is masked by the wide variation in pistoning tendency due to daily reapplication of the orthosis.

Another observation apparent from the data is that resultant mean pistoning constraint forces vary with the functional activity performed, for a given orthotic joint design. As previously described, the pistoning constraint is caused by the conflict or mismatch between complex anatomical and simplified orthotic kinematics. The data indicates that the mismatch varies with the activity performed. This implies that no single-axis-of-rotation orthotic knee joint design (single axis, posterior offset, and optimal single axis), as well as a polycentric design with a single prescribed axis path, can match the variety of kinematical axis pathways which occur during functional activities closely enough to consistently reduce the pistoning constraint. This observation indicates the need for development of a semiconstrained orthotic knee joint which is able to imitate or allow a variety of normal knee motions to freely occur, yet provide appropriate stability for different single or combined ligamentous insufficiencies.

The results of this study provide some guidelines for orthosis design; however, minimizing the pistoning constraint is but one of several design goals or criteria for a knee orthosis. For example, a primary design criterion would be that the orthotic device provide knee stability when necessary to compensate for injured, healing or absent ligaments. This criterion could be evaluated by measuring relative joint motion in an unstable knee both before and after application of an orthosis design. The goal of minimizing the pistoning constraint force, as described in this report, provides a guide to one aspect of knee orthosis design, provides insights into the biomechanics of natural knee and orthotic knee joints, and is hopefully a first step in the direction of rational design and evaluation of knee orthoses.

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REFERENCES

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