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A New Concept in Orthotics— The Northwestern University Knee Orthosis System Part II: The Complete Orthosis

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INTRODUCTION

As stated in an earlier report,[1] when an orthosis is applied to the knee, it should, hypothetically, allow a full, unrestricted range of motion to occur, except at appropriate limits of motion where orthotic constraints are intentionally introduced. This ideal situation is limited by the type of available orthotic joints incorporated into knee orthoses. When using orthotic knee joints which are unable to follow the motion pathways of the natural joint, a tighter fitting interface will magnify the pistoning constraint due to the motion mismatch between the orthotic and natural joint, causing patient discomfort, motion restriction, and misalignment of the orthosis (Lew, et al. (1982)[2]).

In the first part of this report, it was shown that an improved orthotic knee joint system was designed, which decreased the pistoning effect by allowing the orthotic joints to more closely imitate the natural knee kinematics (Lewis, et al. (1983)[1]). These semi-constrained, anatomically-shaped joints allow improvements in orthotic suspension to be realized, since a tighter fitting orthosis with these joints will not increase the pistoning constraint.

A second knee orthosis requirement is that the orthotic interface should be designed to compliment the function of the orthotic joints, in the sense that the interface should be able to be modified to handle particular knee instability problems.

This report will contain a description of a knee orthosis incorporating an improved orthotic joint design, its biomechanical rationale, significant features of the fabrication and fitting process, and a description of several case studies.

Figures 1-A through 1-D present four views of the proposed knee orthosis with "collateral" orthotic joints. The joint sidebars are attached to the proximal and distal interface components, which are in turn circumferentially suspended in the thigh and calf regions by broad straps. To insure

Figure 1-A. Four views of a representative completed orthosis with collateral-type orthotic joints—anterior view.

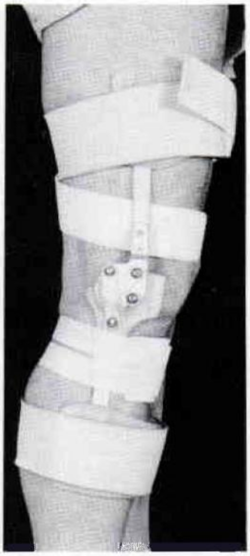


Figure 1-B. Lateral view.

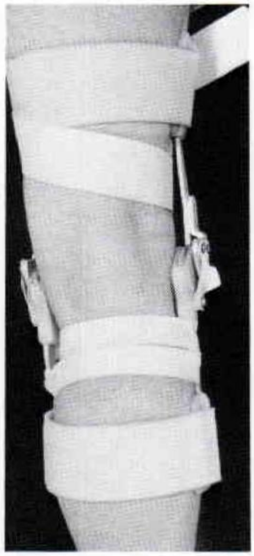


Figure 1-C. Posterior view.

Figure 1-D. Medial view.

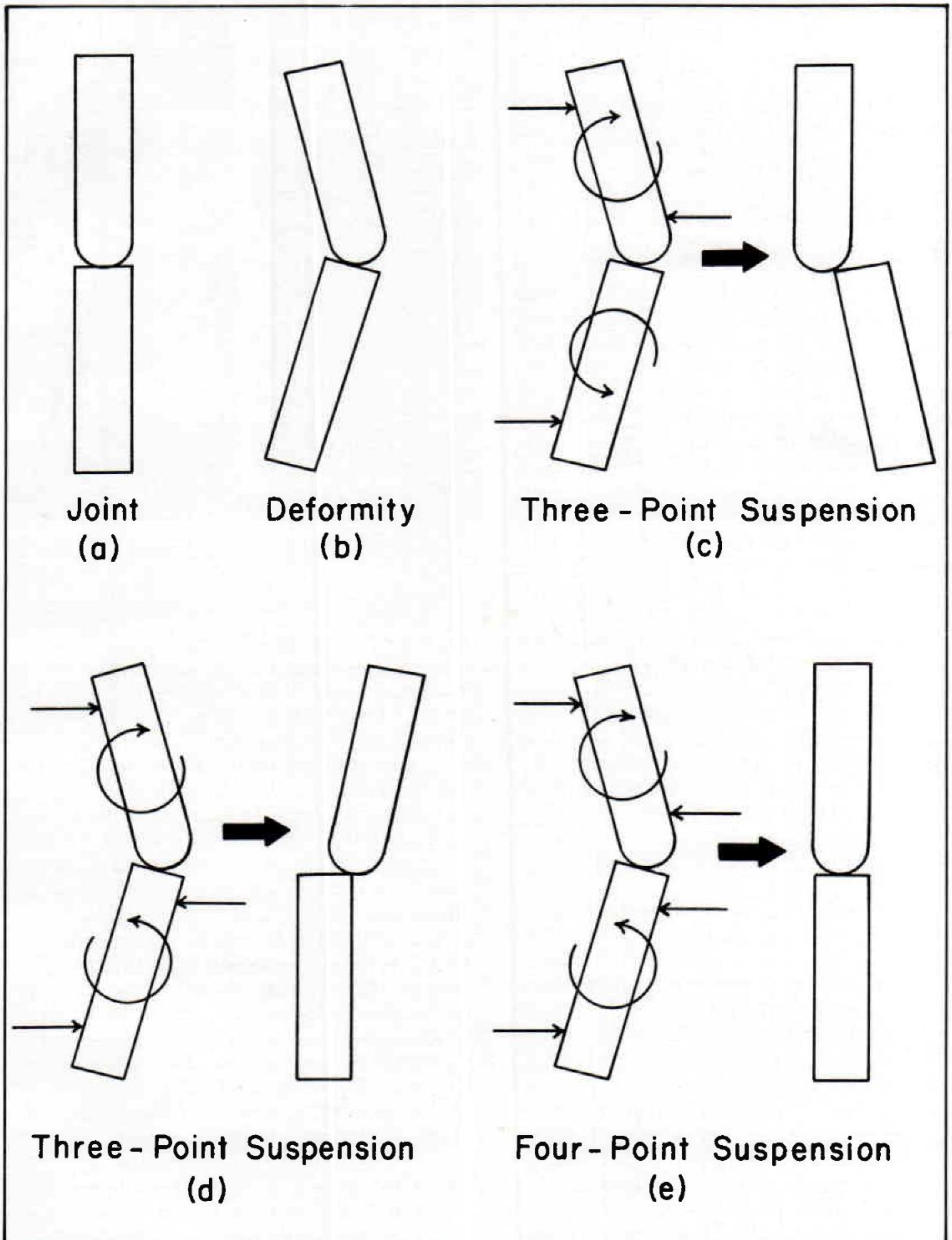
adequate fixation of the orthosis, the interface components are accompanied by a medial femoral suspension pad and a proximal tibial suspension pad, each with its own associated strapping arrangement. Materials of the above orthotic components vary with the application at hand, and will be described later in this report.

BIOMECHANICS OF KNEE ORTHOSIS SUSPENSION

A basic feature of the proposed orthosis is the use of a "four-point" suspension principle rather than a "three-point" fixation, as is commonly practiced in orthotics. Three-point support is suitable for stabilizing a joint if ligamentous integrity and constraint exist across the joint, but is inadequate with a ligamentous deficit, which is frequently the case requiring the application of a knee orthosis.

The limitation of the three-point fixation system in the unstable knee is demonstrated in Figures 2-A through 2-E. When suspension forces are applied to a joint (Figure 2-A) with a deformity (Figure 2-B), the functional forces, and the moments they create, will tend to bend and shear the joint. With three-point support (Figures 2-C, 2-D), one segment of the limb can be held in place at any one instant; however, only one force remains to support the second bony segment. Even though the point of application of this force may remain fixed, the limb segment can rotate about the single support point, causing a shearing or displacement motion at the joint, which is the very motion that is to be prevented. By contrast, as shown in Figure 2-E, a four-point fixation system will allow two suspension points on each limb segment, thus controlling and preventing motion of both segments.

The orthotic interface components and strapping arrangement should be such that, given an instability direction (such as varus, valgus, anterior or posterior drawer, rotational, etc.—any of which can be represented by the sketches in Figures 2-A through 2-E), they are capable of being altered in structure or position, to apply the



Figures 2-A through 2-E. Sketches representing the knee joint and lower limb segments: (A) with a deformity; (B) showing the effect of a "three-point"; (C, D) a "four-point"; (E) orthotic suspension.

four forces and resulting moments necessary to provide stability or correct a deformity, and control motion at the joint. Details concerning the suspension components of the proposed orthosis, together with their application in the restraint of various instabilities, will be presented below.

SIGNIFICANT FABRICATION FEATURES

A standard plaster negative impression is taken of a patient's lower limb. As the plaster sets, constant pressure is applied to the medial femoral supracondylar region, so that the impression retains an accurate description of the individual's anatomy in this area. An accurate impression of the medial tibial flair region is also obtained. The positive plaster impression is then made and modified, with emphasis given to the parallel buildups on both sides of the knee, to ensure that orthotic joints are parallel to each other and perpendicular to the joint space. Sidebars containing the orthotic joint designs are contoured to the positive plaster impression, so that the joint space of each orthotic joint is located at the level of the natural joint space, midway in the anterior-posterior plane of the knee. In the completed orthosis, it is intended to place the orthotic joints as closely as possible to the natural knee joint. Proximal and distal interface components are fabricated by vacuum-forming a thermoplastic over the positive plaster impression. In this process, the orthotic joint sidebars are mechanically thermobonded to the interface, which is itself composed of two layers of thermoplastic thermobonded to each other. Using the medial femoral supracondylar depression on the positive plaster impression, a medial femoral suspension pad is fashioned out of any possible number of materials (acrylic cement, hard rubber, etc.), and is securely attached to the proximal medial joint sidebar. Figures 1-A through 1-D present the four views of a completed orthosis with "collateral" orthotic joints. Details of several features of the orthosis, as well as their rationale, are described below.

INTERFACE SUSPENSION IMPROVEMENTS IN THE NU ORTHOSIS SYSTEM

Medial Femoral Suspension Pad

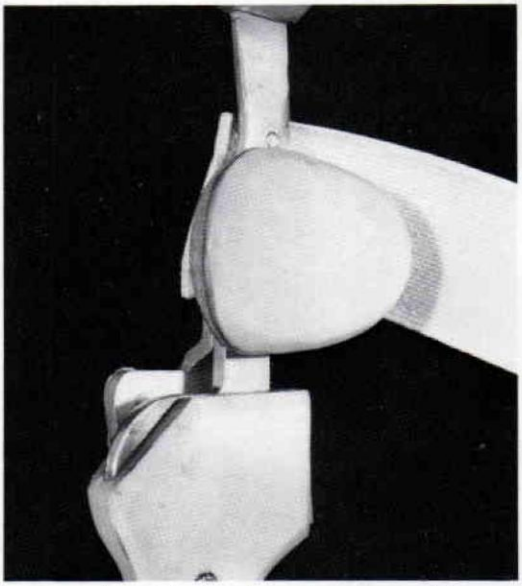


Figure 3-A. Inside view (posterior aspect) of the medial femoral suspension pad. Note the thin layer of padding covering the acrylic cement.

A common problem which occurs with knee orthoses is distal slippage during function. To provide additional resistance to this slipping, the orthosis incorporates a suspension pad in the medial femoral supracondylar region. The basic geometry of this medial femoral suspension pad is shown in Figure 3-A, and its fabrication is described in the previous section of this report. This particular pad is made from a cold-curing acrylic cement with a thin padded covering, although other materials such as hard rubber can be used, depending upon the clinical situation. The thickness of the medial femoral pad can be varied. For example, given a post-surgical or post-injury condition with associated muscular atrophy, the pad can be ground away and resurfaced (decreasing its depth) as the volume of the thigh musculature increases during the rehabilitative physical therapy process.

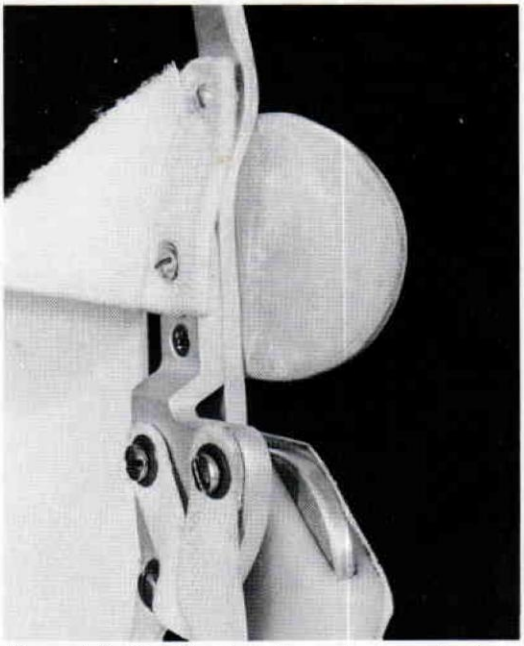


Figure 3-B. Outside view (posterior aspect) of the medial femoral suspension pad and associated strap. Note the pad and strap attachments to the inner and outer surfaces of the medial orthotic sidebar, respectively.

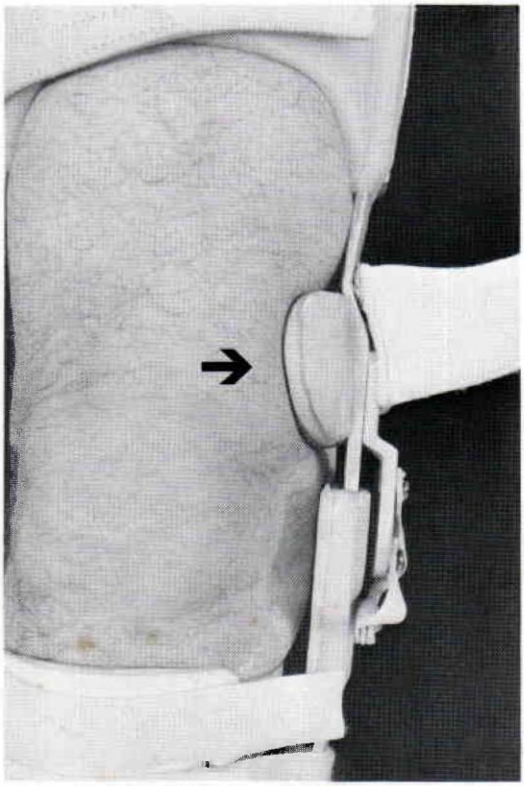


Figure 3-C. Medial femoral pad engages the medial femoral supracondylar region.

Figures 3-B and 3-C show that the medial femoral suspension pad is securely attached to the inner surface of the medial orthotic joint sidebar. To insure that the medial femoral pad is securely placed against the femur, a strap whose origin is on the outer surface of the medial orthotic joint sidebar (Figures 3-B and 3-C) encircles the thigh anteriorly (Figure 3-D), and reattaches over the broad strap of the proximal interface (Figure 3-E). Tightening this strap pulls the thigh (medial femoral supracondylar region) against the medial femoral suspension pad (Figure 3-E). The clinical significance of the forces generated by this pad and strap, as they pertain to the four-point suspension system, will be described later in this report.

Proximal and Distal Interface Components

The design criteria for proximal and distal interface components are that they should be:

- rigid and strong enough to withstand repeated functional loads, or correct and hold a deformity
- lightweight
- unobtrusive and cosmetically acceptable
- comfortable
- able to be modified to generate different combinations of four-point suspension forces

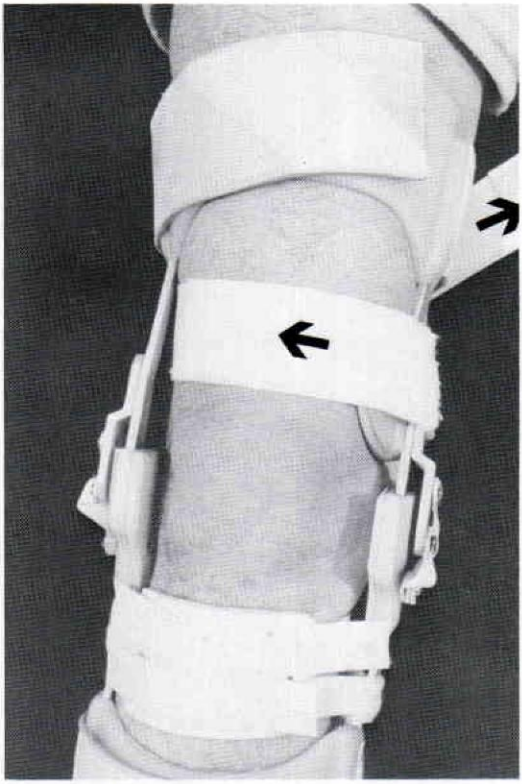


Figure 3-D. Strap for the medial femoral pad encircles the thigh anteriorly, pulling the thigh against the pad.

Figure 3-E. Completed strapping arrangement for the medial femoral suspension pad.

The proximal and distal interface components of the majority of proposed orthoses fabricated to date (particularly athletic applications) consist of a copolymer, with a composition of ten percent polyethylene and 90 percent polypropylene. This type of plastic has excellent rigidity, is lightweight, and is a thermoplastic in that it has good workability with vacuum-forming. A completed orthoses using this co-polymer weighs approximately one and one-half pounds. For some non-athletic applications, an acrylic plastic with a rubber additive (Plexiglass-DR, Rhom, and Haas) is used. This plastic is contact clear and high impact resistant. A third type of interface material, used in geriatric applications, is a foamed polyvinyl chloride (Foamex, Alusuisse Metals, Inc.). It is extremely lightweight, yet has adequate rigidity.

Almost all of the orthoses fabricated to date have been of the posterior opening type (Figures 1-A through 1-D). As described earlier, the proximal and distal interface components are constructed by vacuum-forming two layers of thermoplastic over the positive plaster impression, providing a rigid interface along with a method of mechanically attaching the orthotic joint sidebars (Figure 1-D). The interface components are suspended circumferentially in the thigh and calf regions by broad straps composed of gum rubber with a leather backing. These straps originate (attached with rivets) just posterior to the thermobonded sidebars, encircle the limb segments, and attach again via Velcro® strips on the anterior surfaces of the proximal and distal components. Note that the straps avoid the popliteal region, insuring patient comfort. This plastic and strapping arrangement provides for rigid interface components, yet, because of the strapping, the components can accommodate the volume changes of the lower limb musculature during activities.

Because of the vacuum-forming technique, the trim lines of the proximal and distal interface components can be modified to the specific clinical situation at hand. Figures 1-A through 1-D show typically-shaped interface components. However, if the orthosis is intended to correct certain deformities, as will be described in some of the case studies, the proximal and distal interface component trim lines can be altered, creating a more broad or localized component, depending upon the situation.

Proximal Tibial Suspension Pad

The proximal tibial suspension pad and two associated straps are situated just proximal to the distal interface component, distal to the joint space (refer to Figure 4-A). The pad is fabricated by heat forming Foamex (Alusuisse Metals, Inc.) over the tibial tubercle region of the positive plaster impression, and is attached with a short strap to the lateral joint sidebar.

The first step in donning the proximal tibial pad is to encircle the upper calf region with the top strap in Figure 4-A, such that it passes posteriorly under the medial joint sidebar (Figure 4-B), around the calf and over the lateral joint sidebar, and attaches with Velcro® on the anterior surface of the proximal tibial pad (Figure 4-C). The bottom strap in Figure 4-A is then looped around the medial joint sidebar (Figure 4-D), passed around the upper calf region, over the lateral sidebar, and becomes attached with Velcro® on the anterior surface of the proximal tibial pad (Figure 4-E).

The force system generated by the proximal tibial pad and straps in Figures 4-A through 4-E is shown by the cross sectional sketches in Figure 5-A and 5-B.

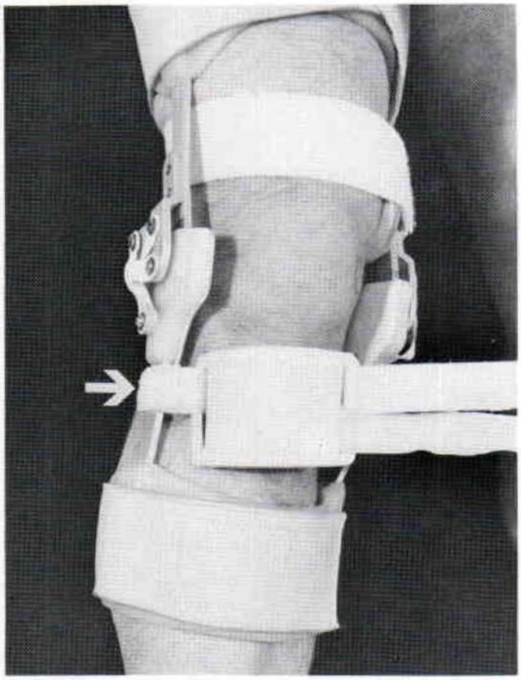


Figure 4-A. Proximal tibial suspension pad with two associated straps. Note that the pad is attached to the lateral orthotic joint sidebar.

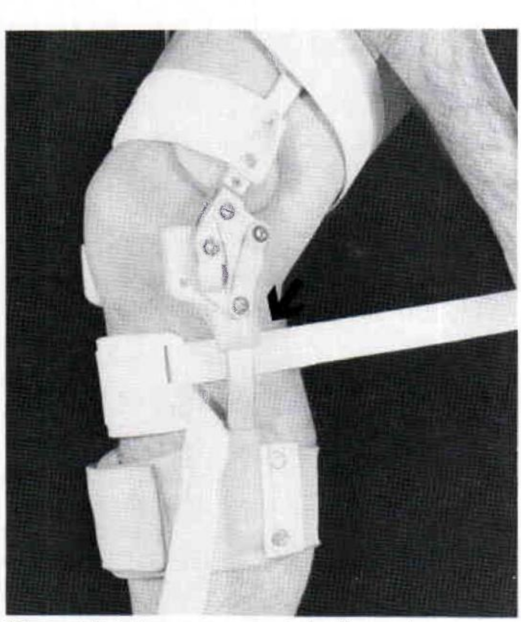


Figure 4-B. The upper strap is the first to be secured, as it is passed under the medial joint sidebar and around the upper calf region.

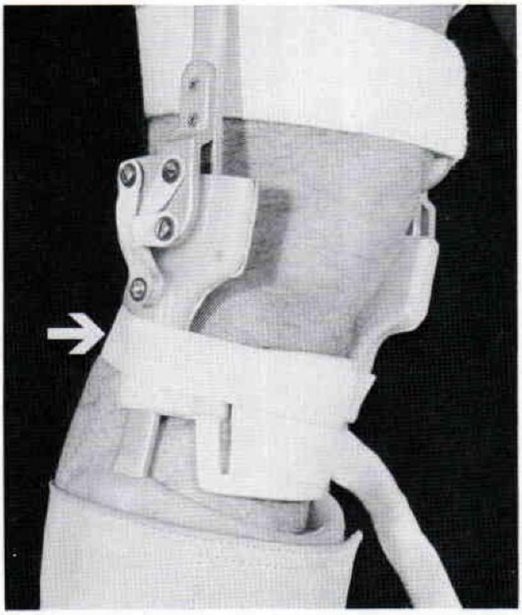


Figure 4-C. The upper strap continues around the posterior calf, and passes over the lateral joint sidebar. The upper strap is secured by a Velcro® bond to the anterior surface of the proximal tibial pad.

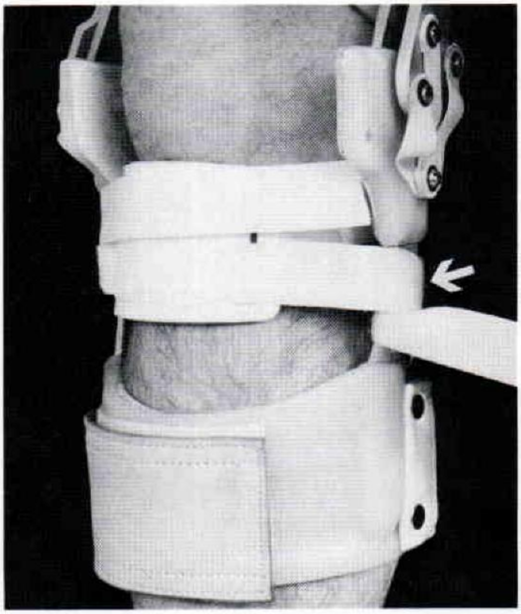


Figure 4-D. The lower strap is initially looped around the medial joint sidebar.

When the pad is attached to the lateral joint sidebar, and the top strap (the one which encircles the calf itself) is tightened, the pad and strap create a moment which forces the tibial pad to pivot about the lateral joint sidebar, displacing it posteriorly and rotating it internally (Figure 5-A). The bottom strap, on the other hand, acts to hold the upper tibia in its neutral position, providing a limit to the action of the top strap. This type of arrangement would be used on a knee with an anteriolateral instability (anterior cruciate-lateral capsule insufficiency), since it would prevent this instability by forcing the knee posteriorly and into internal rotation.

If the strapping arrangement was such that the proximal tibial pad was initially attached to the medial rather than lateral joint sidebar, tightening the top strap would force the tibia posteriorly and rotate it externally (Figure 5-B). This arrangement would be used to restrain a knee with an antero-medial instability (anterior cruciate-medial collateral and/or medial capsule

Figure 4-E. The lower strap is then passed around the upper calf, outside of the lateral sidebar, and is secured by a Velcro® strip on the anterior surface of the proximal tibial pad. Both upper and lower straps are properly attached in this photograph, securing the proximal pad to the limb and orthosis.

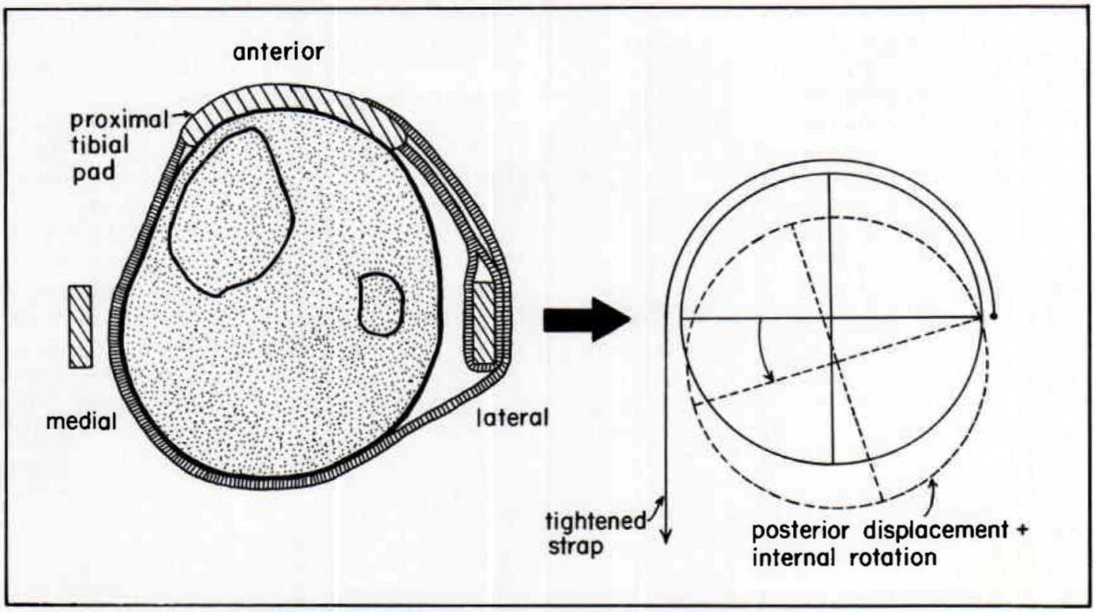


Figure 5-A. If the proximal tibial pad is attached to the lateral joint sidebar, tightening the upper strap in Figure 4-A—which encircles the calf itself—displaces the tibia posteriorly and rotates it internally.

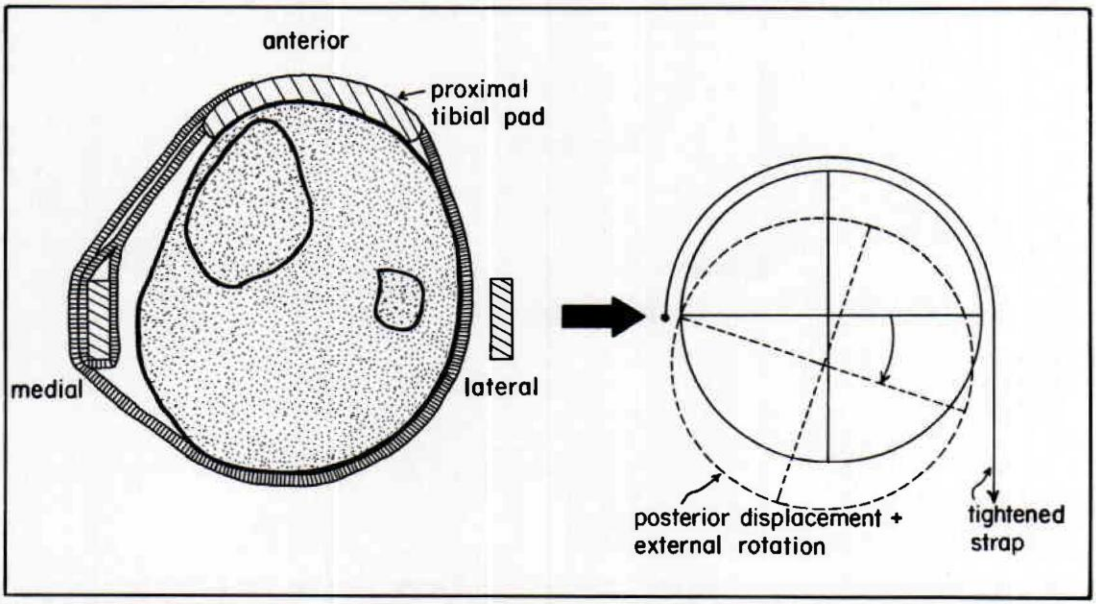


Figure 5-B. If the proximal tibial pad is attached to the medial orthotic joint sidebar, tightening the upper strap displaces the tibia posteriorly and rotates it externally.

insufficiency). Note that in this case, the proximal tibial pad straps are applied in the same way as described above, the only difference being that the pad is secured to the medial rather than lateral joint sidebar.

The following is an example of how the proximal tibial pad can interact with the other suspension components to provide knee stability. If an orthosis is placed on a knee with the objective of reducing anterior displacement of the tibia, the proximal tibial pad is placed anteriorly, as in Figures 4-A through 4-E. The four-point suspension forces generated by the orthosis are shown by the sketch in Figure 6-A. When combined with the anteriorly-directed force of the distal interface component, the posteriorly-directed force of the proximal tibial pad creates a moment which forces the tibia posteriorly, as well as straightens the tibia, thus preventing it from pivoting about the distal interface component. The anteriorly-directed force of the proximal interface component combines with the posteriorly-directed force of the medial femoral suspension pad (with its strap encircling the thigh anteriorly, thereby forcing the thigh posteriorly) to create a moment controlling the motion proximal to the joint. Thus, the above four forces limit the anterior displacement of the tibia and control the motion at the joint.

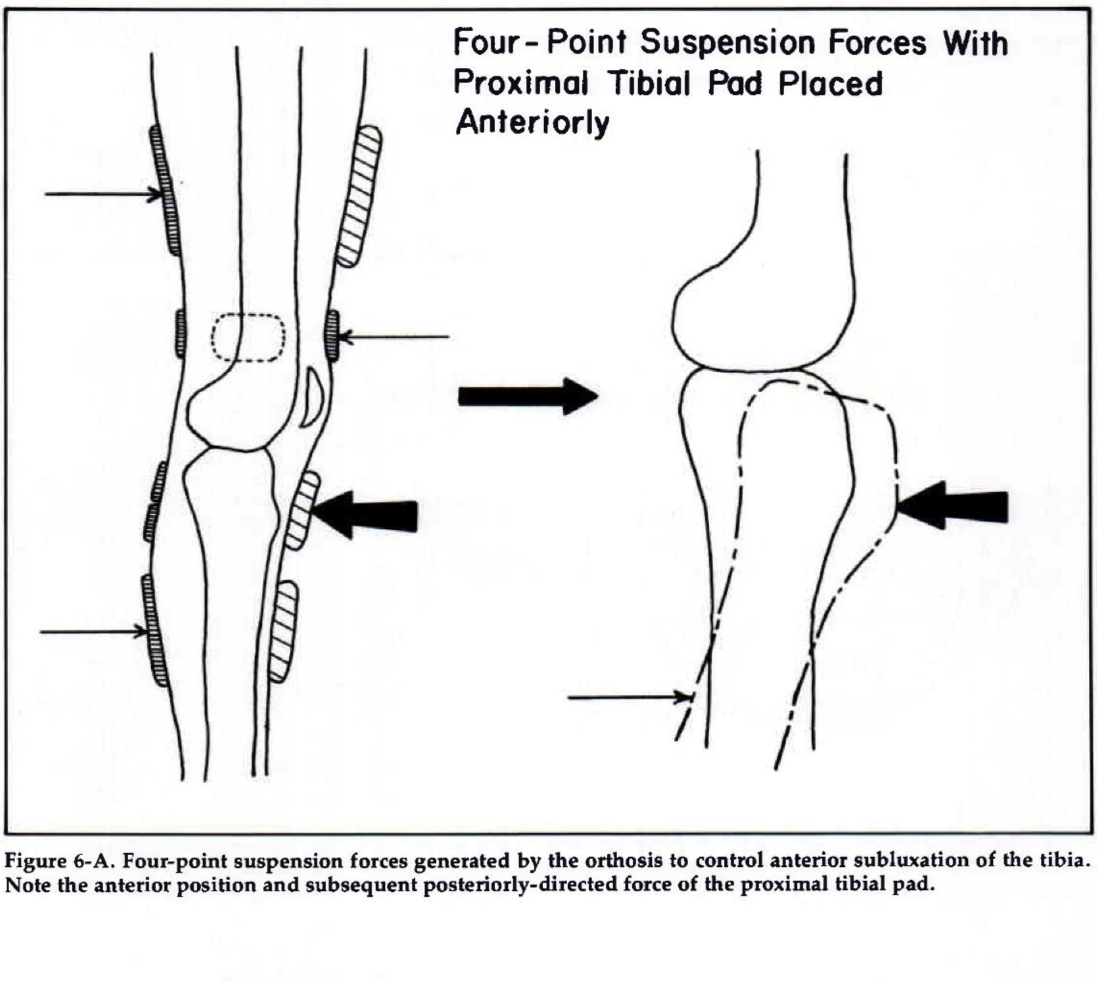


Figure 6-A. Four-point suspension forces generated by the orthosis to control anterior subluxation of the tibia. Note the anterior position and subsequent posteriorly-directed force of the proximal tibial pad.

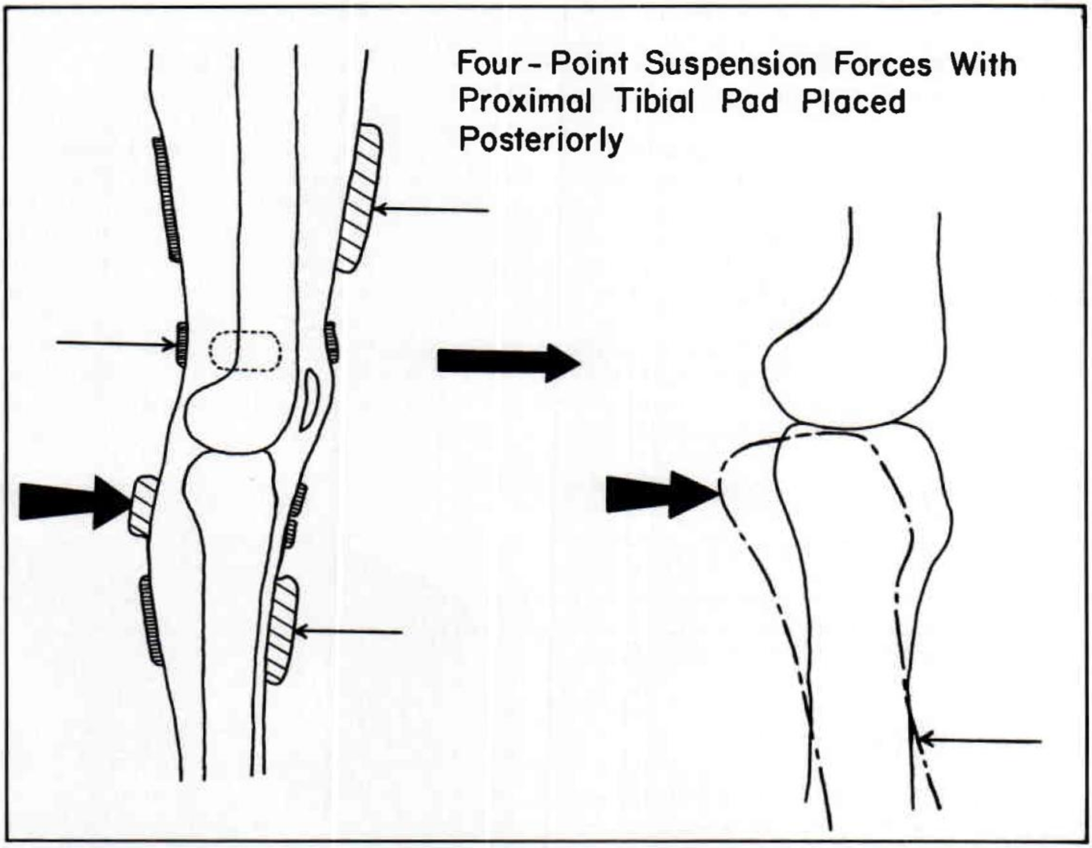


Figure 6-B. Four-point suspension forces generated by the orthosis to control posterior subluxation of the tibia. Note the posterior position and anteriorly-directed force of the proximal tibial pad.

If the orthotic objective was to control posterior subluxation at the knee, the proximal tibial pad can be placed posteriorly as demonstrated in Figure 6-B. The sketch shows that the anteriorly-directed force of the proximal tibial pad combines with the posteriorly-directed force of the distal interface component to create a moment which straightens the tibia and forces it anteriorly. The posteriorly-directed force of the proximal interface component combines with the medial femoral pad's anteriorly-directed force (obtained by its strap encircling the thigh posteriorly), controlling the motion proximal to the joint. Thus, the above four forces limit the posterior displacement of the tibia and control the motion at the joint.

COMMON FITTING MODIFICATIONS

Several modifications of the previously described interface components can be easily made at the time of fitting. The medial femoral suspension pad can be removed, and can be increased or decreased in size depending upon the individual's musculature volume change. The co-polymer thermoplastic of the proximal and distal interface components can be easily heated and flaired away from problem pressure areas. The plastic can also be conveniently ground away for comfort considerations. Note that the fit of the knee orthosis should be extremely intimate, and the system was designed to be worn directly against the skin. Given the fact that the improved orthotic joints minimize the pistoning constraint, tightly fitting interface components insure a functionally efficient and reliable knee orthosis system, while at the same time providing for patient comfort and a cosmetically acceptable result.

ORTHOTIC EVALUATION

To date, approximately seventy patients have been fit with the orthosis. Subjective results have been very satisfactory. A detailed clinical evaluation is in progress, and will be reported in the future. We are also attempting to develop more objective orthotic evaluation criteria, based upon both clinical and mechanical (laboratory) evaluations. To provide some idea of the types of patients being fit in this series of clinical trials, as well as their early results, a description of several case reports will follow.

CASE STUDIES

Case #1: A twenty-two year old female collegiate basketball player sustained an acute injury to the anterior cruciate and medial collateral ligaments of her left knee. She underwent surgery, having an arthrotomy, a medial collateral ligament repair, a pes anserine transfer, and a medial menisectomy. We evaluated her at a point in time nine months post-surgery. Her affected knee exhibited anterior laxity, an antero-medial rotatory instability, and a valgus deformity, but had a negative pivot shift test. The orthotic goal in this case was to stabilize her chronically unstable knee resulting from her injury and repair surgery.

She was fit with an orthosis with a hybrid combination of anterior cruciate and collateral ligament straps (Figure 7). The three collateral straps limited her valgus instability throughout the flexion range, and the one anterior cruciate strap (which tightened at 45 degree flexion) limited the anterior displacement in her knee. In the sagittal plane, the interface components and strapping resisted the anterior displacement of the tibia by generating the four-point suspension forces shown in Figure 6-A. Since an antero-medial rotatory instability was present (tibia internally rotates), the proximal tibial suspension pad was attached to the medial orthotic sidebar, similar to that shown in Figure 5-B. Thus, tightening the proximal tibial pad straps pre-positioned the tibia in external rotation, limiting the antero-medial instability. After being fit with the orthosis, the patient has been able to resume vigorous athletic activity, including basketball, while wearing the orthosis.

Figure 7. An orthosis for the patient in Case Study #1, providing correction for her antero-medial rotatory instability. Note the hybrid ligament strap combination (three collateral straps and an anterior cruciate strap which tightens at 45 degrees of flexion), as well as the use of the co-polymer thermoplastic.

Case #2: A twenty year old male (6'-5½", 240 lbs.), who plays basketball for a local university, injured his right knee when he went up for a rebound, and came down off-balance while simultaneously being hit by another player. An examination revealed an antero-medial rotatory instability, with a possible anterior cruciate injury.

At a later date, he reinjured the same knee, this time sustaining a partial tear of the medial collateral and anterior cruciate ligaments. He was put in a long leg cast, a prepatory orthosis, and finally, after some knee rehabilitation, the definitive orthosis shown in Figure 8.

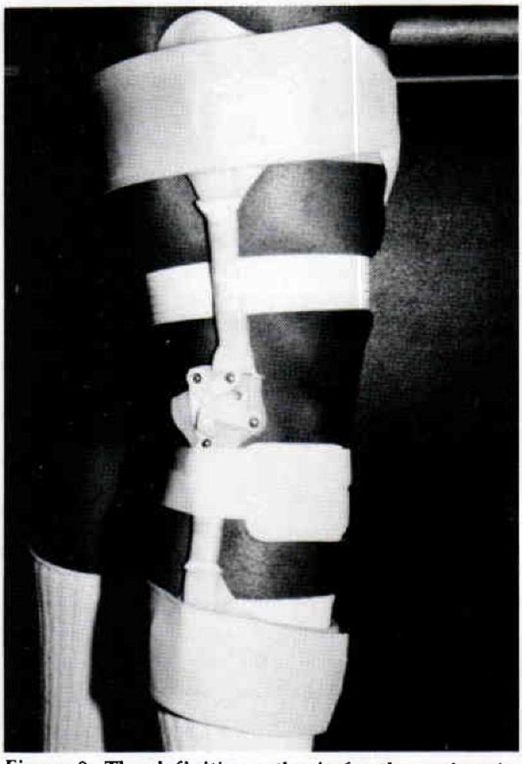


Figure 8. The definitive orthosis for the patient in Case Study #2. The orthosis is the same basic design as in Figure 7.

The construction of the orthosis is the same as that for the patient in the first case, with the hybrid anterior cruciate-collateral ligament straps being used. The patient has been able to resume his athletic activities since being fit with the orthosis.

Case #3: A fifteen year old female sustained a torn left posterior cruciate ligament from a "dashboard injury" during an automobile accident. The torn posterior cruciate was surgically repaired by a modified Jones procedure.

The patient also developed a large pressure sore on her mid-posterior calf from the postoperative cast. The orthotic objective in this case was to prevent knee motions and loads which would load or disrupt the posterior cruciate repair, thus protecting it while it heals, and allowing the patient to undergo a physical therapy program.

The patient was initially fit with a preparatory orthosis (described below) with posterior cruciate orthotic joints. The preparatory orthosis allowed the patient to complete a physical therapy program, rebuilding her lower limb musculature, and provided stability while normal walking was restored. The orthosis was initially fit so as not to impinge upon the pressure sore region, allowing it to rapidly heal.

Four months postoperatively, as her musculature volume increased to near normal, she was fit with a definitive posterior cruciate orthosis (Figure 9). The posterior cruciate orthotic joints were used in conjunction with the posterior placement of the proximal tibial pad, and normal posterior-opening proximal and distal interface components. Note that the interface material for this non-athletic application is Plexiglass-DR. The patient was soon able to resume many daily functional activities while the ligament repair continued to heal.

The preparatory orthosis mentioned in the above case study is intended to provide stability during the period between the plaster fracture orthosis and a definitive knee orthosis. As shown in Figure 10, the preparatory orthosis is fabricated by wrapping a set of orthotic joints in a temporary interface material such as Scotch-Cast (3M Company). The proximal tibial suspension pad is also included. This type of orthosis is used in situations (post-surgical or post-injury) in which the lower limb musculature has atrophied, and when the patient will subsequently undergo physical therapy. During this time, the lower limb musculature will increase in volume with the therapy, thus making it impractical to fabricate several "definitive" orthoses during this relatively brief period. Instead, the preparatory orthoses are easily, cheaply, and reliably applied as needed, as the musculature volume changes, with the patient being fit with the definitive orthosis only when the lower limb has stabilized at its normal geometry.

Case #4: A twenty-one year old male sustained a hyperextension-type injury to both knees. Examination of his left knee revealed a fracture of the medial tibial plateau, and an antero-lateral rotatory instability. His right knee exhibited both antero-lateral and posterolateral rotatory instabilities.

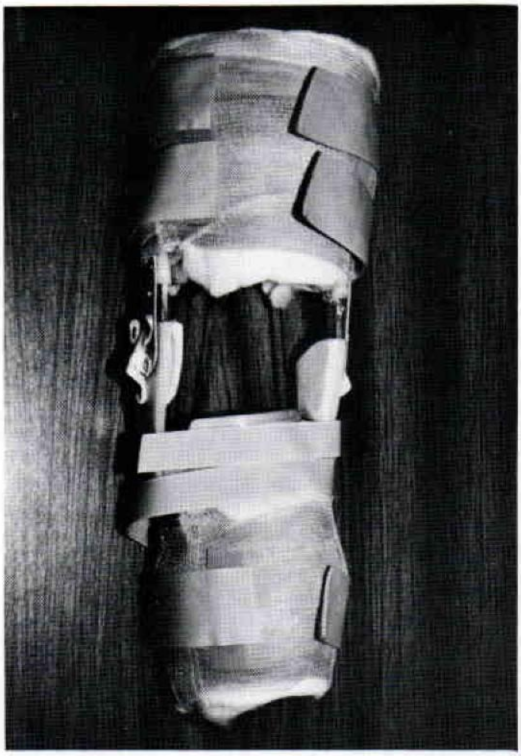


Figure 10. A typical prepatory orthosis design using ScotchCast (3M Company), incorporating collateral orthotic joints and an anteriorly-placed proximal tibial pad.

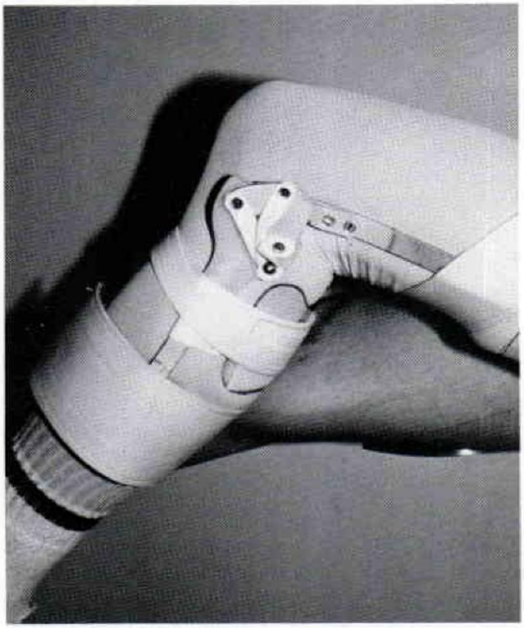


Figure 9. Posterior cruciate orthosis design for the patient in Case Study #3. Note the posterior cruciate orthotic joints (ligament straps), and the posterior position of the proximal tibial suspension pad. The four-point suspension in this case is the same as in the sketch of Figure 6-B. The interface material used was clear Plexiglass-DR.

The patient underwent surgery, having a partial medial menisectomy of his right knee, as well as a repair to the anterior cruciate ligament and posterolateral capsule of the same knee. The orthotic objective for his right knee was post-surgical in nature; that is, preventing the repaired structures from becoming loaded. Since the patient also presented with a marked posterior instability, a special distal interface was fabricated and used in conjuction with an anteriorly-placed proximal tibial pad and posterior cruciate ligament straps (Figures 11-A and 11-B). The distal interface was closed both anteriorly and posteriorly, keeping the knee in its neutral anterior-posterior position during flex-

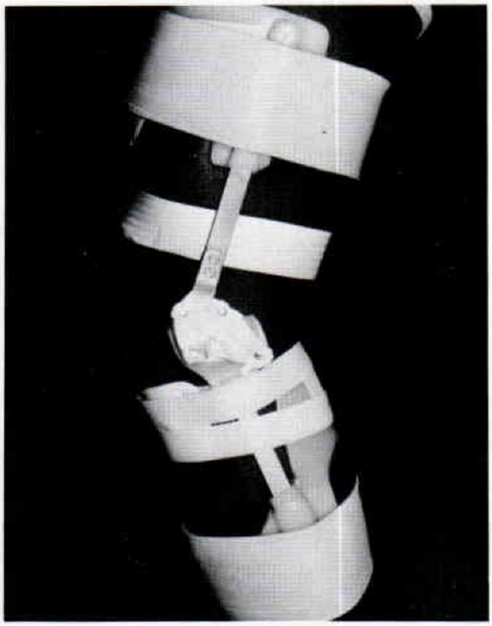


Figure 11-A. The definitive orthosis for the subject of Case Study #4. Note the anterior position of the proximal tibial pad, the fact that the distal interface is closed both anteriorly and posteriorly, and the presence of the posterior cruciate ligament straps.

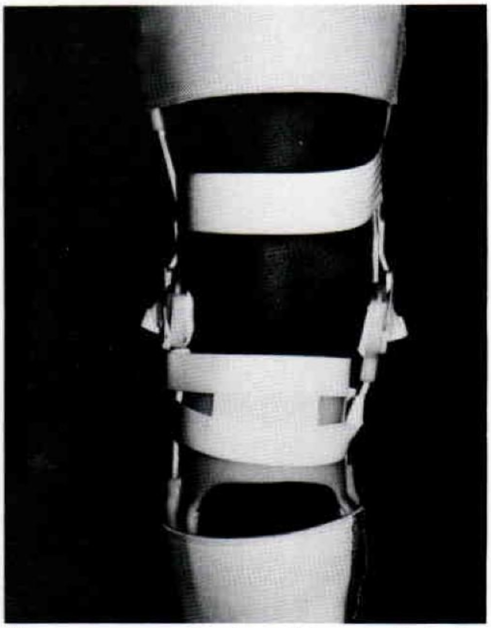


Figure 11-B. Posterior view of the orthosis for the patient in Case Study #4.

ion-extension, and allowing the repaired tissue to heal. The proximal tibial pad was attached to the lateral orthotic sidebar, restraining the anterolateral instability as shown in Figure 5-A. The patient also eventually received a conventional posterior-opened orthosis with collateral ligament straps to provide restraint for the chronic antero-lateral rotatory instability in his left knee.

DISCUSSION

We have applied our knee orthosis to a wide range of patient problems, including those with chronic ligamentous laxity, post-traumatic instability, postoperative ligamentous reconstructions, patients with total knee replacements, post-polio applications, as well as others. These probably represent the spectrum of potential users of knee orthoses. The results to date have been quite satisfactory. There have been complaints common to all knee orthoses, such as cosmesis and inconvenience, but generally, the clinical results have fulfilled our design expectations of a tighter fitting, more functional orthosis, by virtue of the improved anatomically shaped orthotic joints. Subjectively, results have been better than our previous experience with other commercially available orthoses. A formal clinical evaluation will be reported in the near future.

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