Spring, 1984
Volume 38
Number 1

Orthotics and Prosthetics

Journal of the American Orthotic and Prosthetic Association

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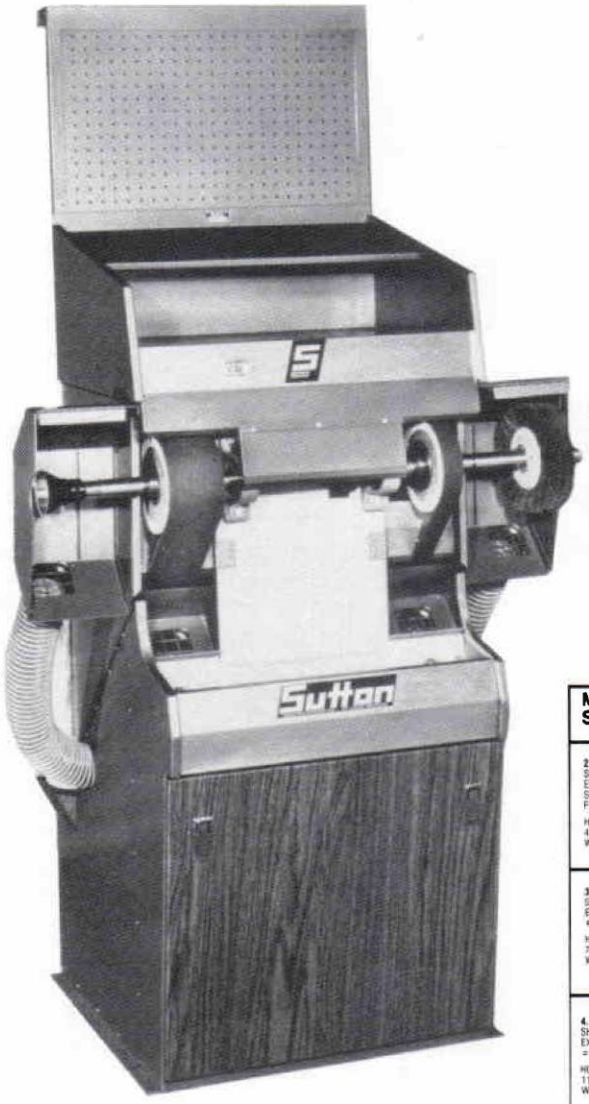

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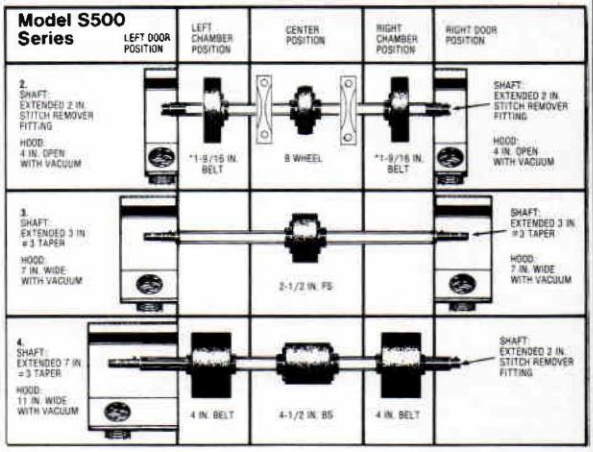

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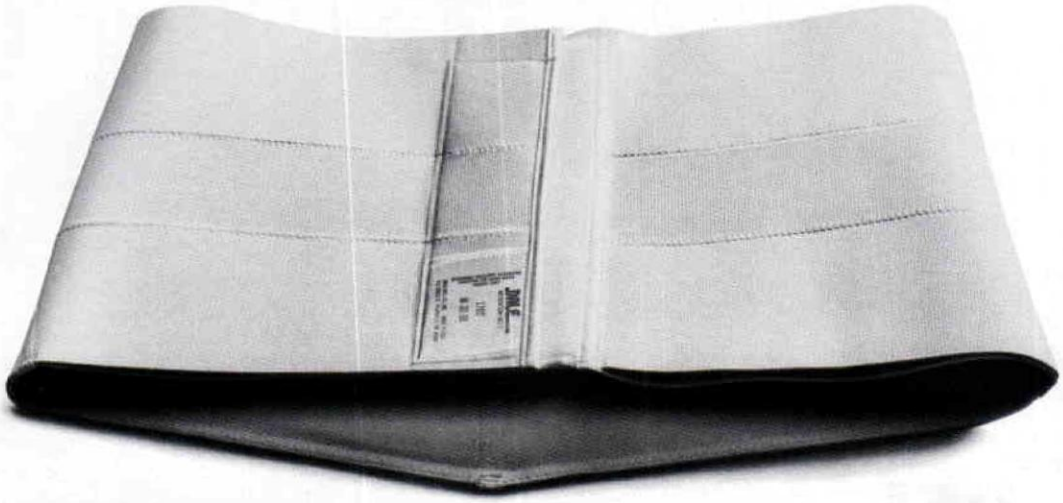

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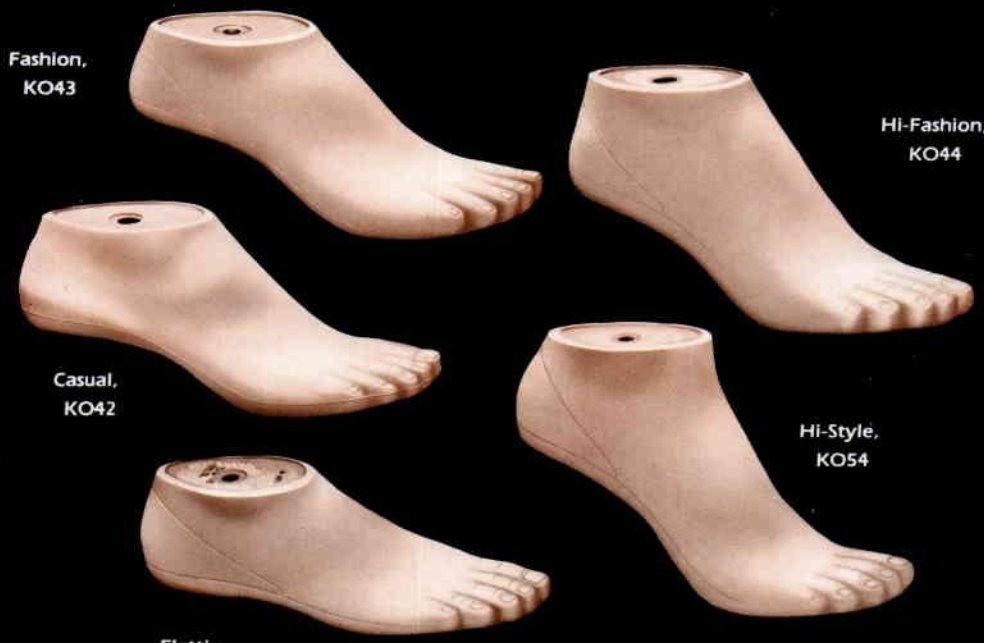

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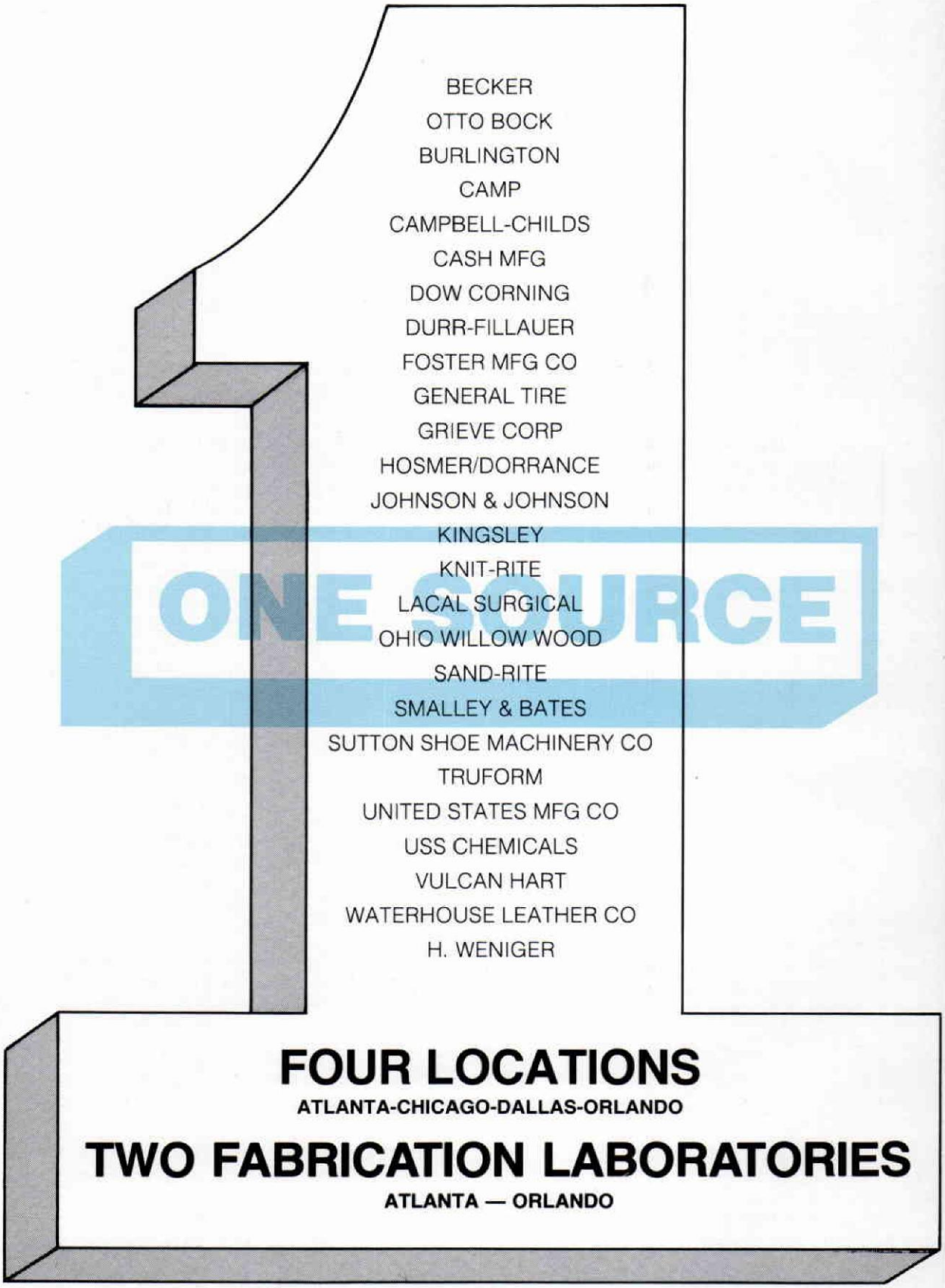

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June 4–8, 15th World Congress of Rehabilitation International on the theme of "Information, Awareness, and Understanding for Integration of Disabled Persons and Society," Lisbon, Portugal. Contact: (Program) Rehabilitation International, 432 Park Avenue South, New York, New York 10016.

June 6–8, Electric Elbow Seminar, Newington Children's Center, Newington, Connecticut. Presented by Hosmer Dorrance Corporation. Contact: Catherine Wooten, 561 Division Street, Campbell, California 95008; 408-379-5151.

June 9–10, Florida Academy Chapter and Florida Association Combined Meeting, Holiday Inn Surfside, Clearwater, Florida.

June 12–July 4, 7th World Wheelchair Games (formerly Paralympics), University of Illinois, Champaign, Illinois. Contact: Prof. Timothy Nugent, Rehabilitation Education Center, 1207 South Oak Street, Champaign, Illinois 61820.

June 16–28, 1984 International Games for the Disabled, sponsored by the International Sports Organization for the Disabled, Nassau County, Long Island, New York. Contact: Mr. Michael Mushett, Director, 1984 International Games for the Disabled, c/o Special Populations Unit, Eisenhower Park, East Meadow, New York 11554.

June 17–22, "1984—The Bright Side," The Second International Conference on Rehabilitation Engineering, combined with the 7th Annual Conference on Rehabilitation Engineering, Congress Centre, Ottawa, Ontario, Canada. Sponsored by the National Research Council of Canada, the Rehabilitation Engineering Society of North America, and the Canadian Medical and Biological Engineering Society. Contact: Conference Services, National Research Council of Canada, Ottawa, Ontario, Canada K1A 0R6.

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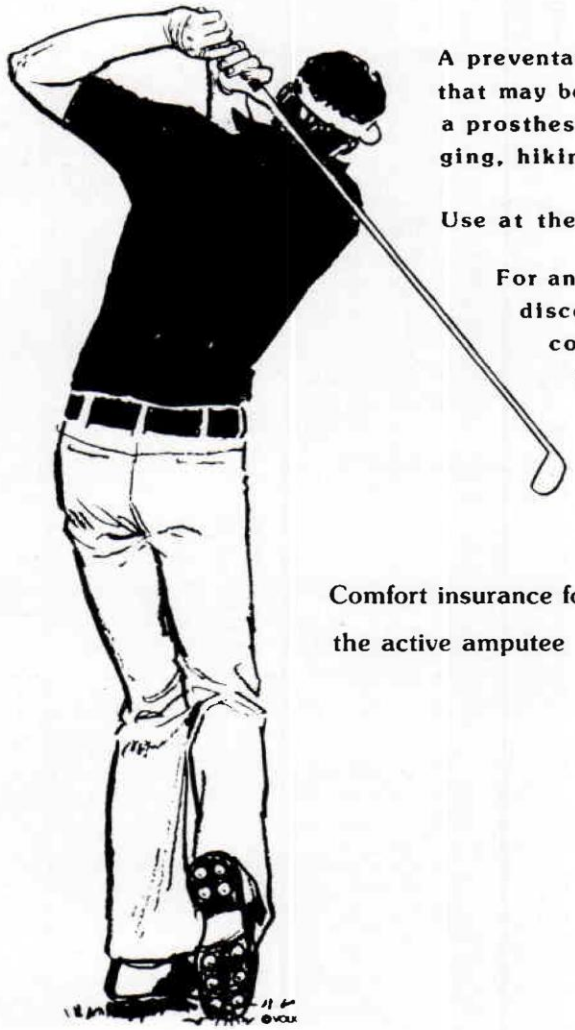

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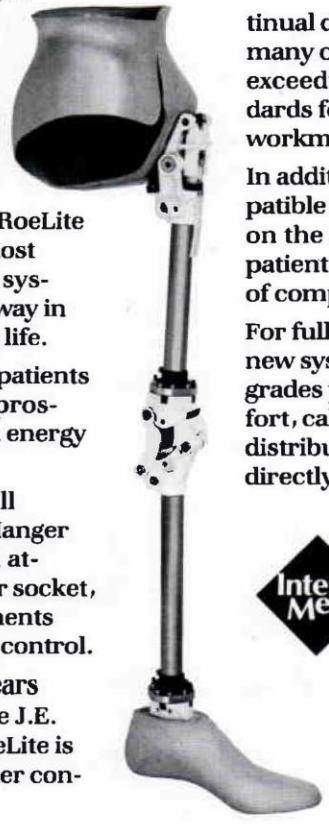

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Orthotics and Prosthetics, Volume 38, Number 1, Spring, 1984, pp. 13–28.

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

Jack L. Lewis, Ph.D.
William D. Lew, M.S.
S. David Stulberg, M.D.
Carl M. Patrnchak, R.P.T., C.O.
George T. Shybut, M.D.

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

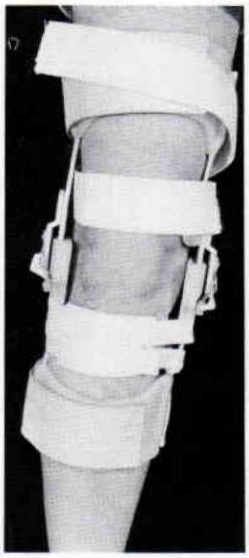


Figure 1-A. Four views of a representative completed orthosis with collateral-type orthotic joints—anterior view.

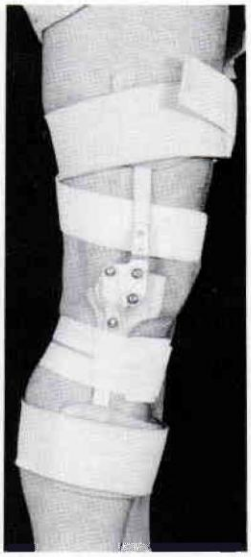


Figure 1-B. Lateral view.

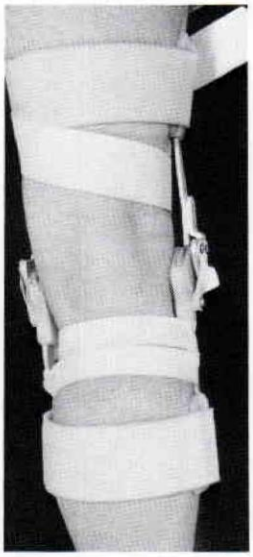


Figure 1-C. Posterior view.

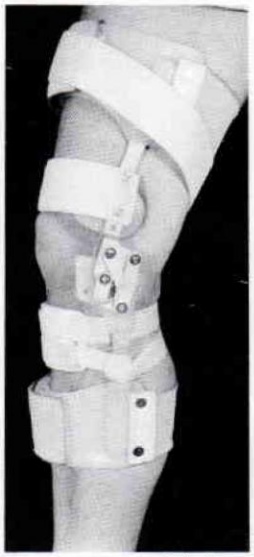


Figure 1-D. Medial view.

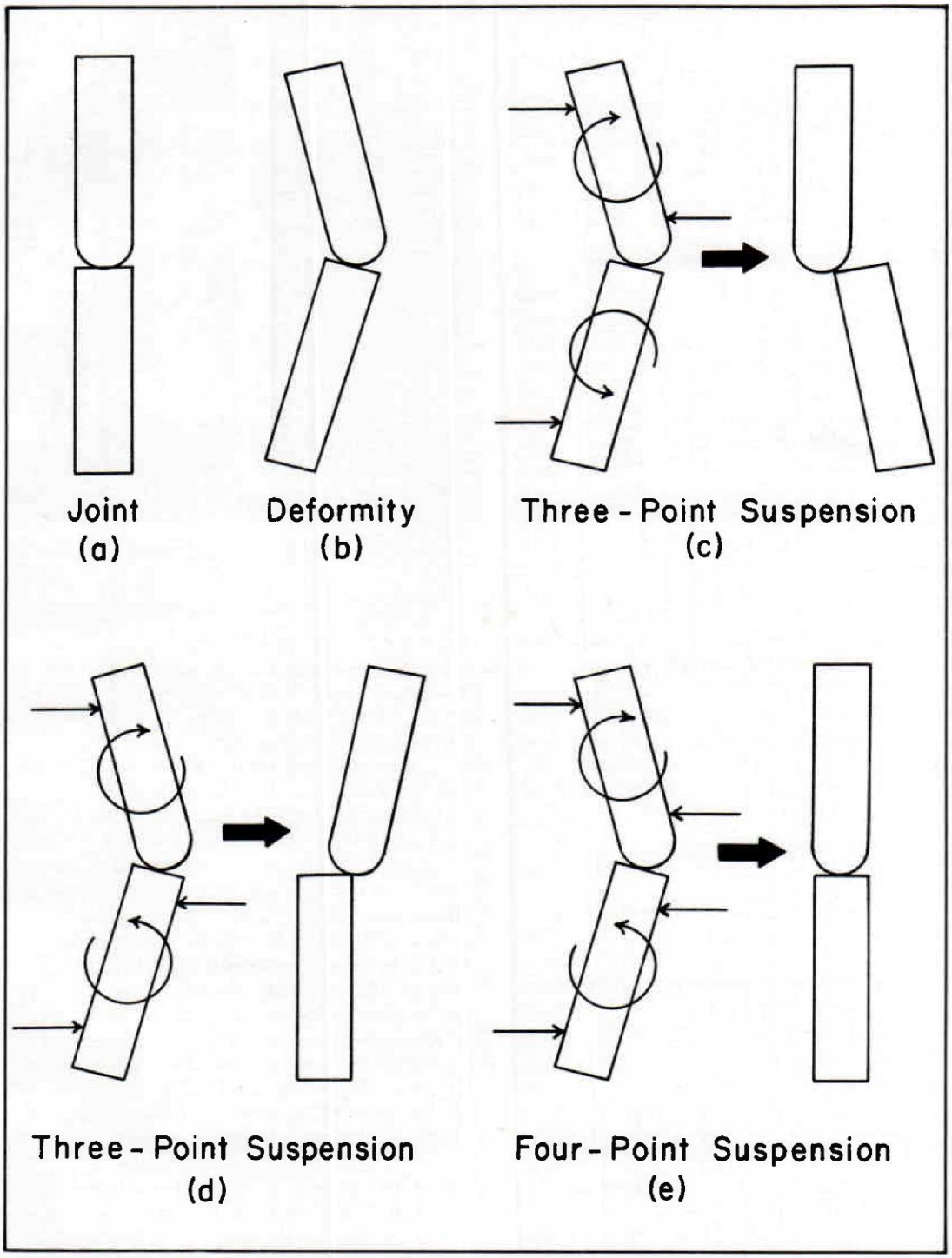
adequate fixation of the orthosis, the interface components are accompanied by a medial femoral suspension pad and a proximal tibial suspension pad, each with its own associated strapping arrangement. Materials of the above orthotic components vary with the application at hand, and will be described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

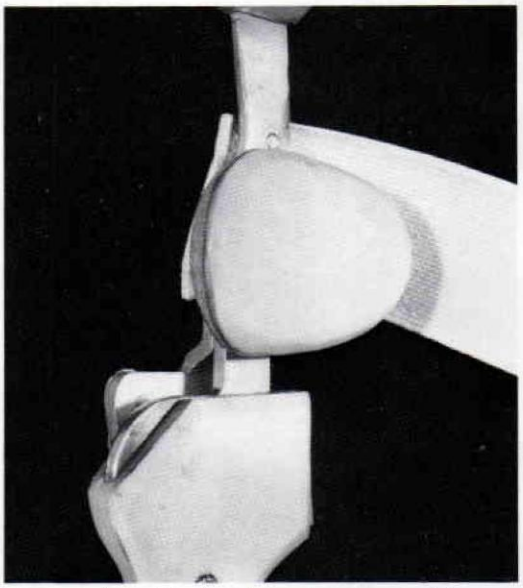


Figure 3-A. Inside view (posterior aspect) of the medial femoral suspension pad. Note the thin layer of padding covering the acrylic cement.

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.

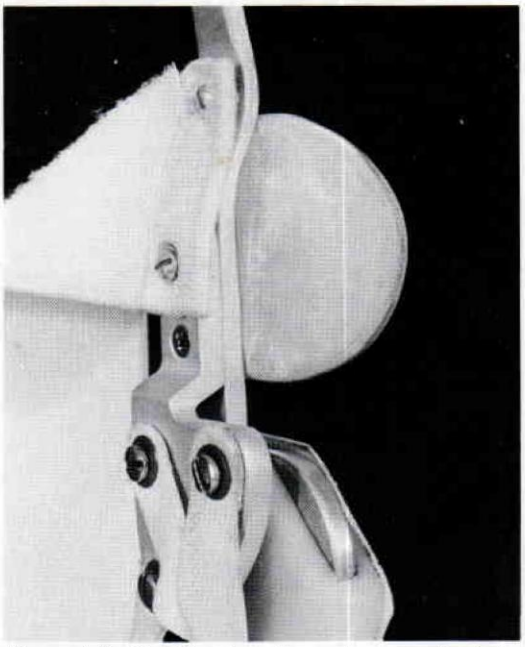


Figure 3-B. Outside view (posterior aspect) of the medial femoral suspension pad and associated strap. Note the pad and strap attachments to the inner and outer surfaces of the medial orthotic sidebar, respectively.

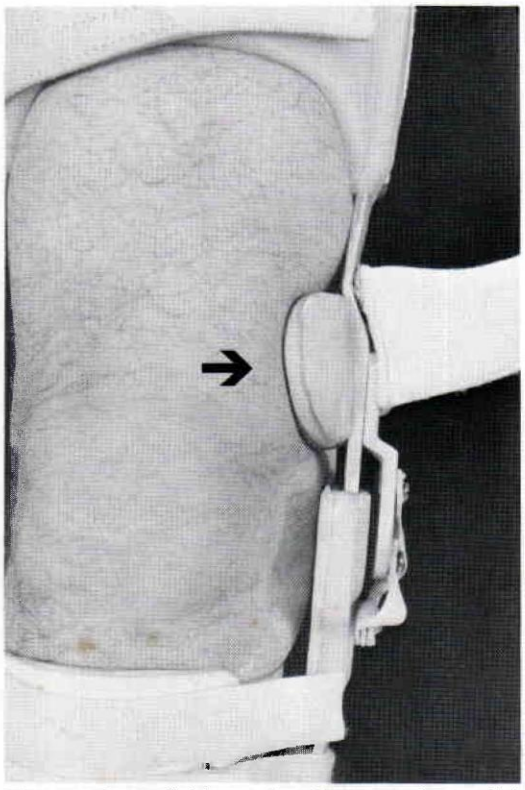


Figure 3-C. Medial femoral pad engages the medial femoral supracondylar region.

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

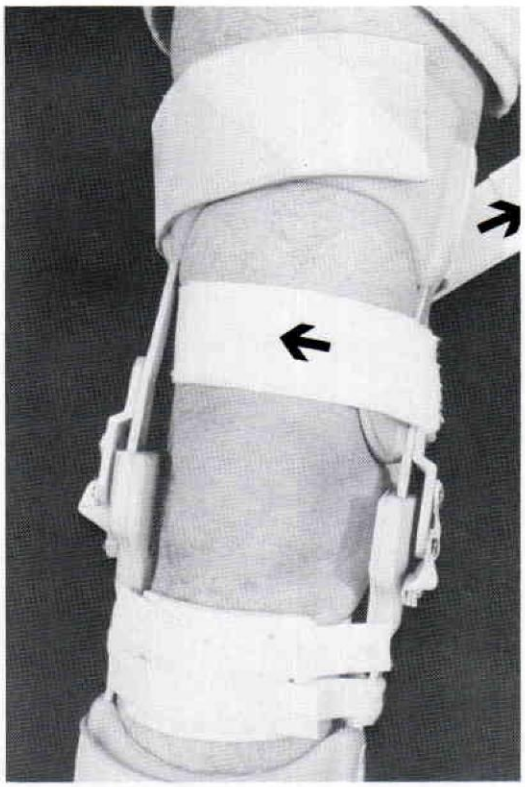


Figure 3-D. Strap for the medial femoral pad encircles the thigh anteriorly, pulling the thigh against the pad.

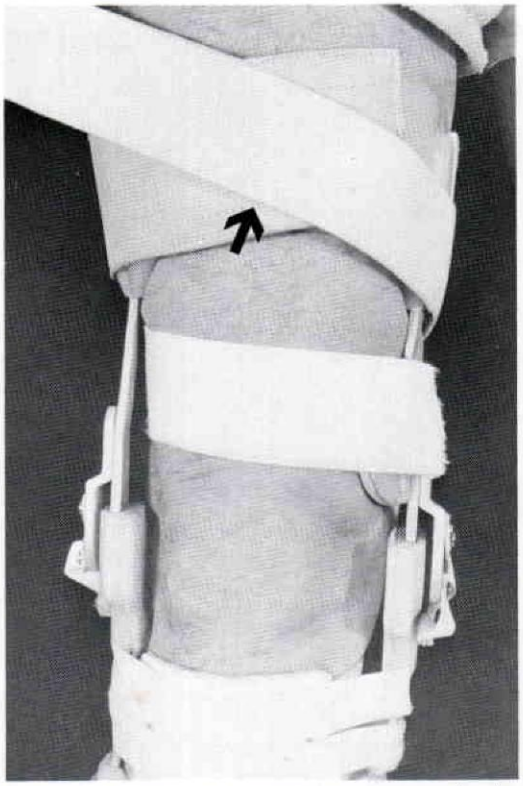


Figure 3-E. Completed strapping arrangement for the medial femoral suspension pad.

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.

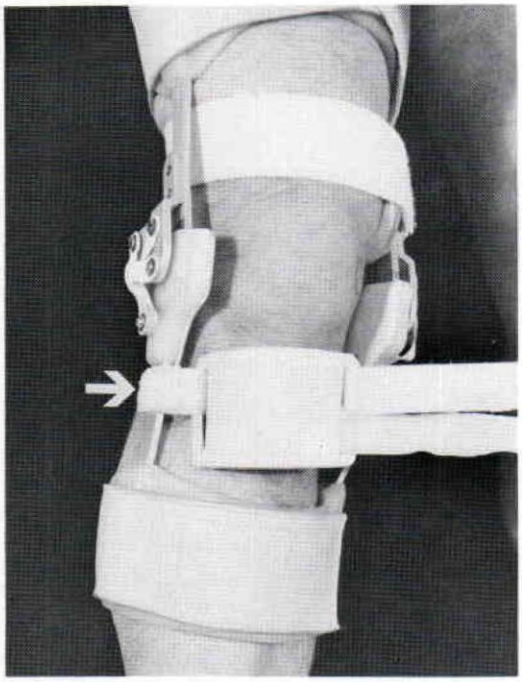


Figure 4-A. Proximal tibial suspension pad with two associated straps. Note that the pad is attached to the lateral orthotic joint sidebar.

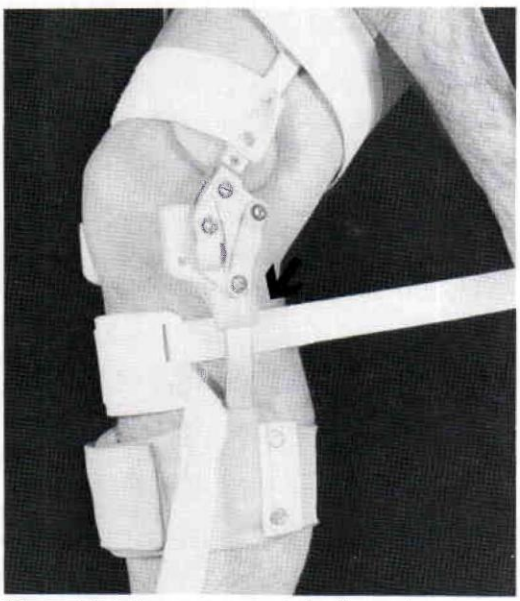


Figure 4-B. The upper strap is the first to be secured, as it is passed under the medial joint sidebar and around the upper calf region.

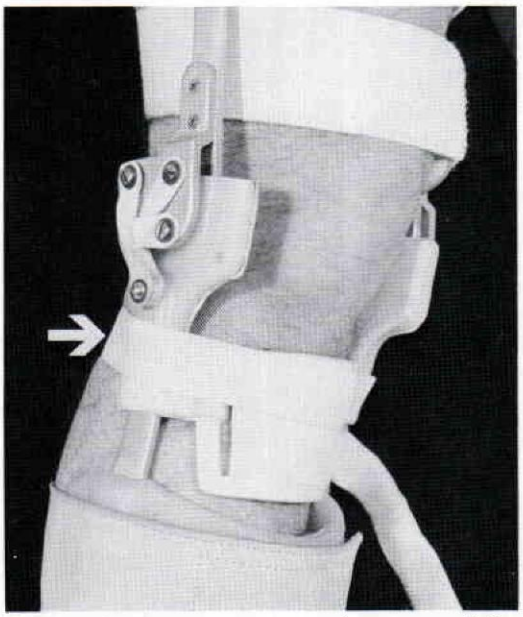


Figure 4-C. The upper strap continues around the posterior calf, and passes over the lateral joint sidebar. The upper strap is secured by a Velcro® bond to the anterior surface of the proximal tibial pad.

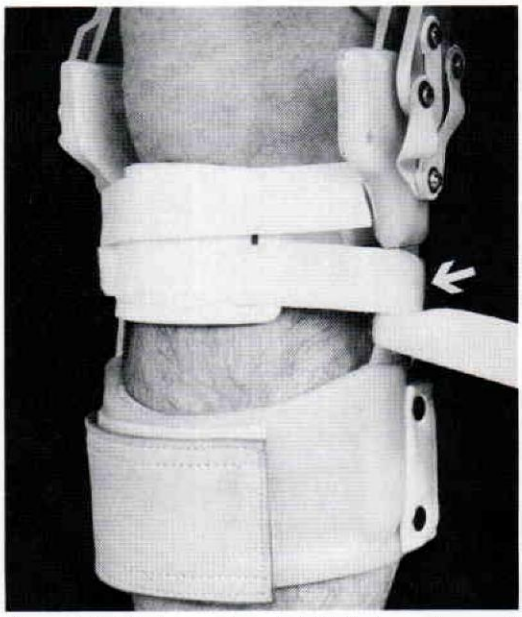


Figure 4-D. The lower strap is initially looped around the medial joint sidebar.

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

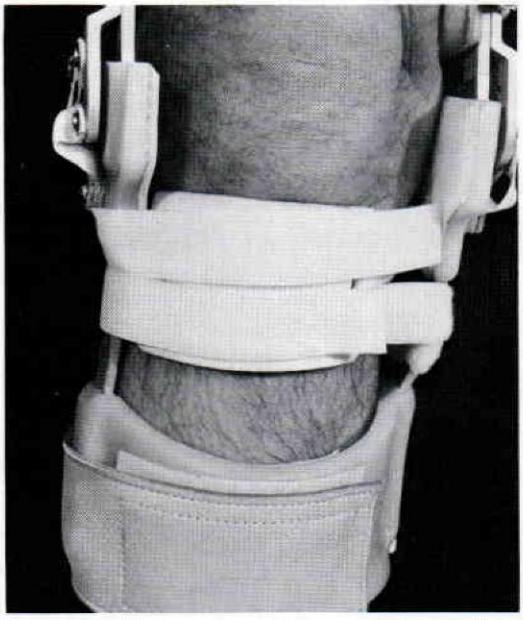


Figure 4-E. The lower strap is then passed around the upper calf, outside of the lateral sidebar, and is secured by a Velcro® strip on the anterior surface of the proximal tibial pad. Both upper and lower straps are properly attached in this photograph, securing the proximal pad to the limb and orthosis.

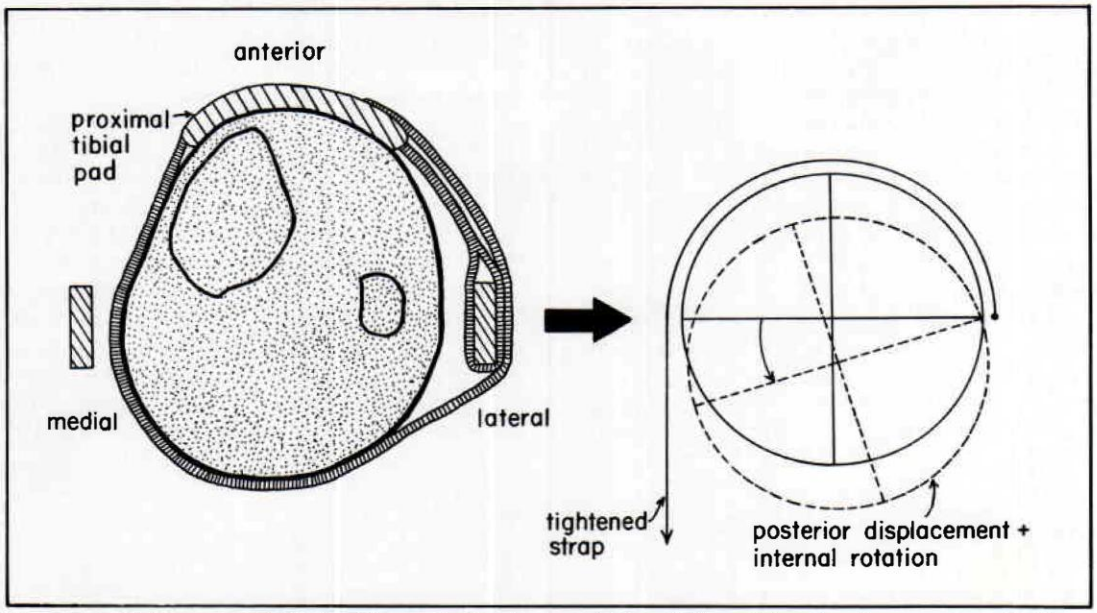


Figure 5-A. If the proximal tibial pad is attached to the lateral joint sidebar, tightening the upper strap in Figure 4-A—which encircles the calf itself—displaces the tibia posteriorly and rotates it internally.

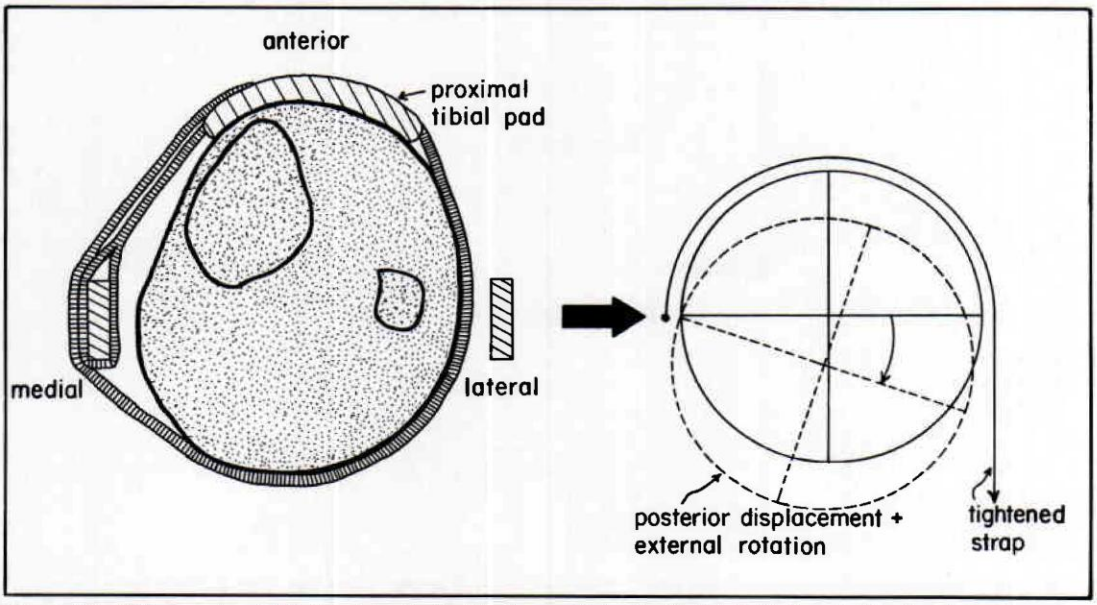


Figure 5-B. If the proximal tibial pad is attached to the medial orthotic joint sidebar, tightening the upper strap displaces the tibia posteriorly and rotates it externally.

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.

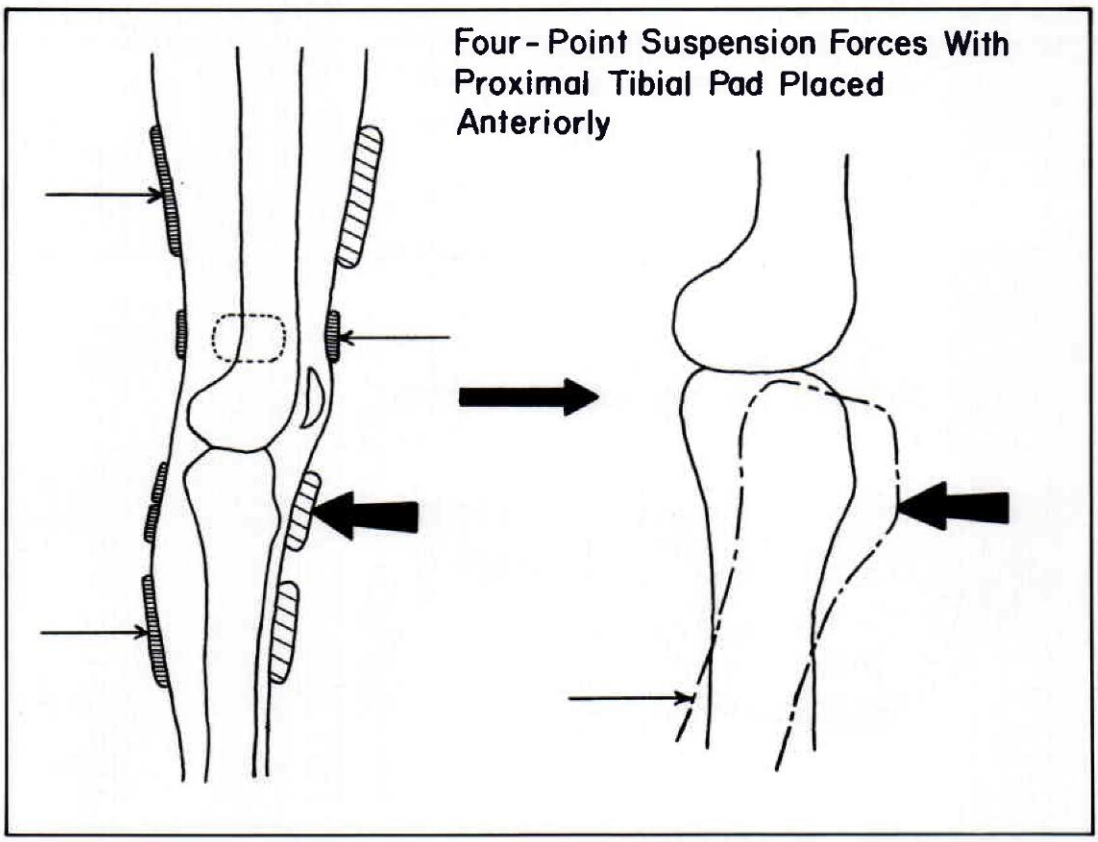


Figure 6-A. Four-point suspension forces generated by the orthosis to control anterior subluxation of the tibia. Note the anterior position and subsequent posteriorly-directed force of the proximal tibial pad.

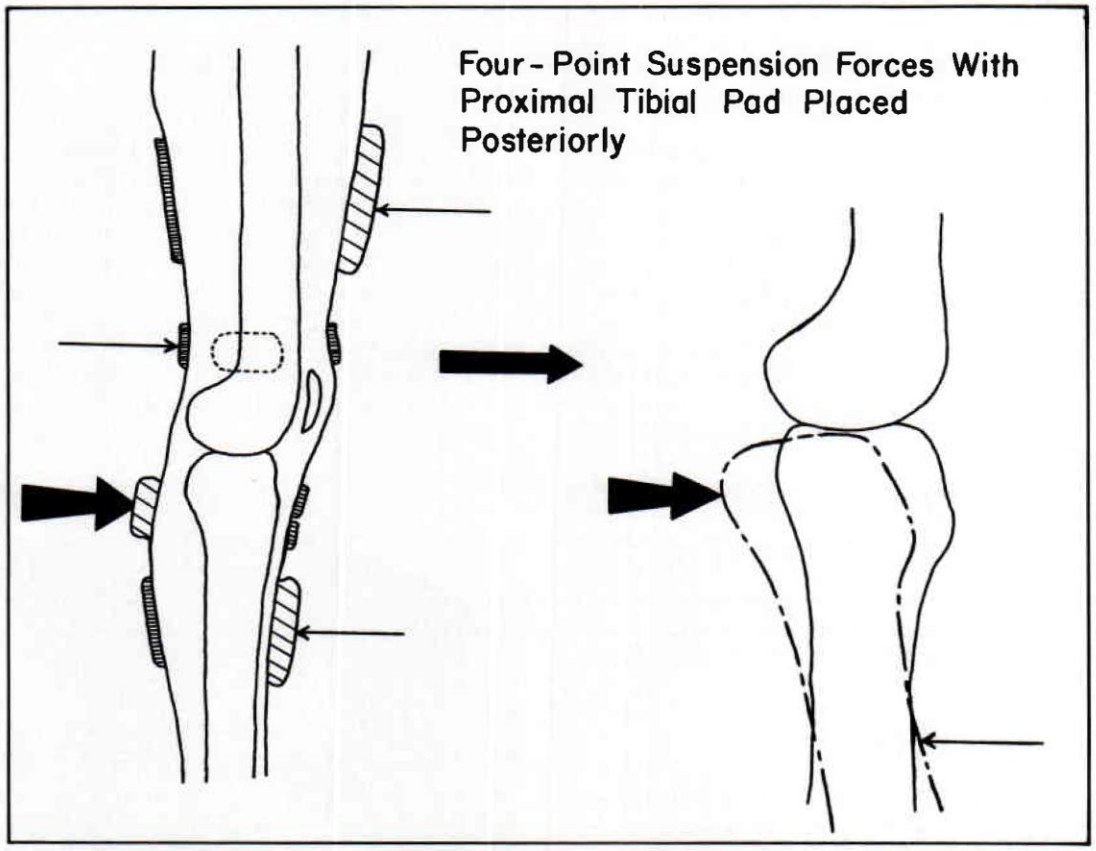


Figure 6-B. Four-point suspension forces generated by the orthosis to control posterior subluxation of the tibia. Note the posterior position and anteriorly-directed force of the proximal tibial pad.

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 di-

rectly 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.

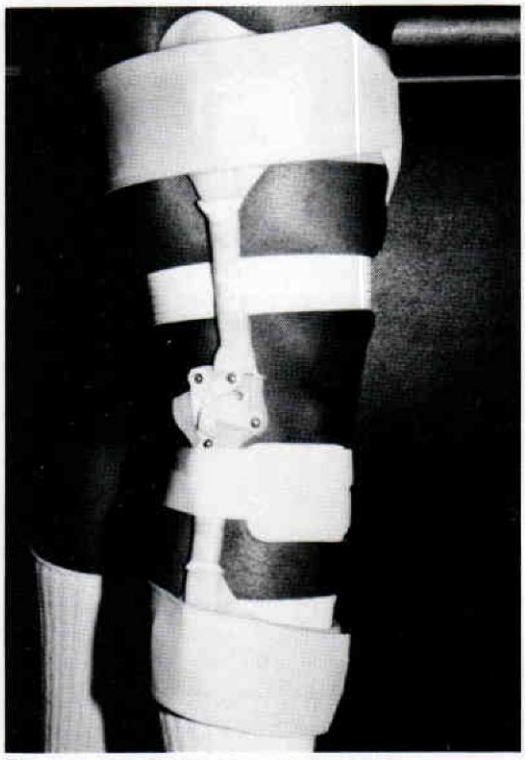


Figure 8. The definitive orthosis for the patient in Case Study #2. The orthosis is the same basic design as in Figure 7.

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.

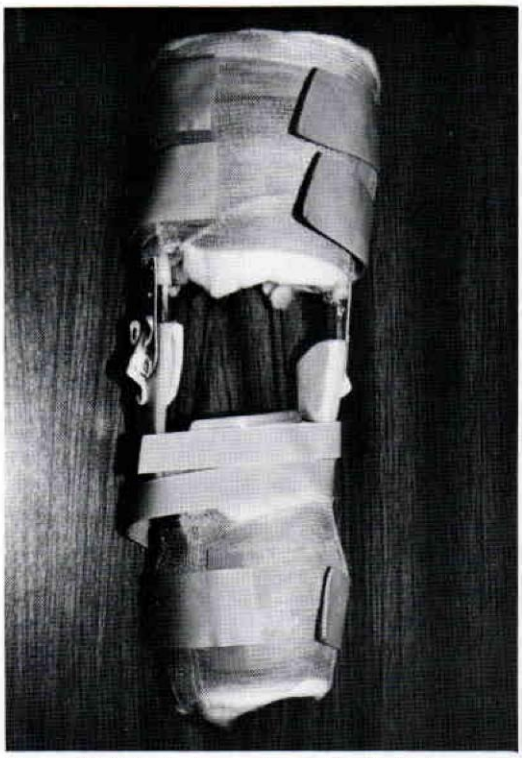


Figure 10. A typical prepatory orthosis design using ScotchCast (3M Company), incorporating collateral orthotic joints and an anteriorly-placed proximal tibial pad.

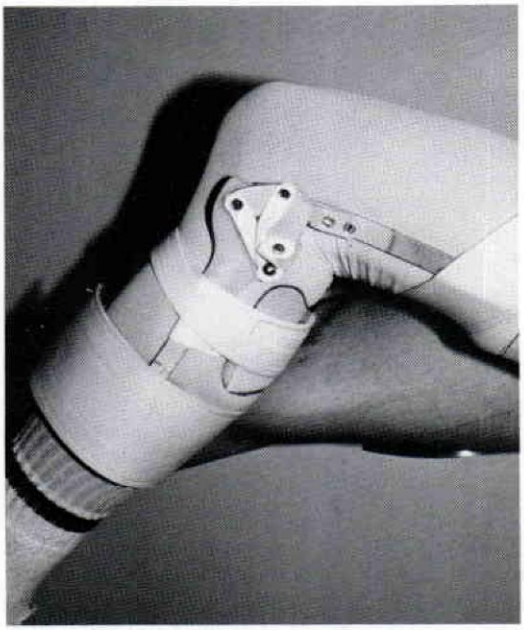


Figure 9. Posterior cruciate orthosis design for the patient in Case Study #3. Note the posterior cruciate orthotic joints (ligament straps), and the posterior position of the proximal tibial suspension pad. The four-point suspension in this case is the same as in the sketch of Figure 6-B. The interface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

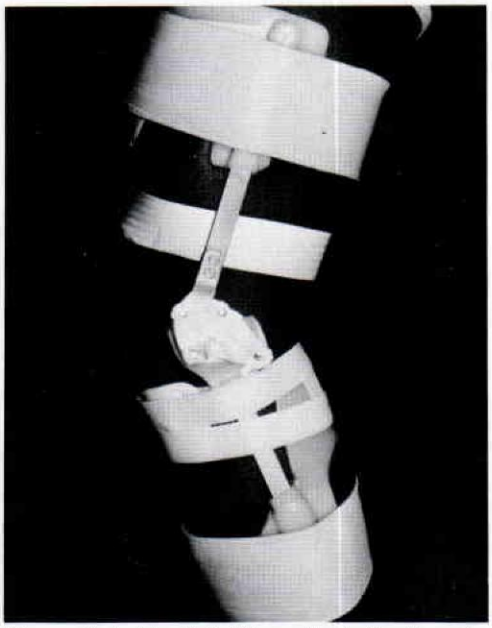


Figure 11-A. The definitive orthosis for the subject of Case Study #4. Note the anterior position of the proximal tibial pad, the fact that the distal interface is closed both anteriorly and posteriorly, and the presence of the posterior cruciate ligament straps.

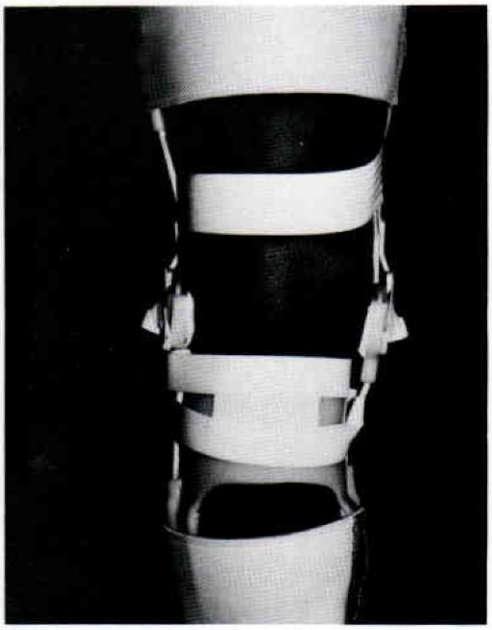


Figure 11-B. Posterior view of the orthosis for the patient in Case Study #4.

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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Ottawa Experience With Hip Disarticulation Prostheses

Tony van der Waarde, C.P. (C), F.C.B.C.

INTRODUCTION

By far the greatest rejection rate among prosthesis users in the group of lower limb amputees is that of the high level amputee, i.e., very short above-knee, hip disarticulation, and complete or incomplete hemipelvectomies (or trans-pelvis amputations). In order to assess the state of the art in these categories, a study was initiated in 1980 among patients who had failed to gain satisfaction from their prostheses and had ultimately resorted to ambulation on crutches rather than be restricted by ungainly and awkward artificial limbs.

Numerous letters written to well-respected prosthetists, physicians and rehabilitation engineers around the world solicited opinions on the apparent lack of success in fitting these clients. After compiling the data from these sources, and an extensive literature search, no definitive protocol or fitting technique emerged to be used as a base for further development (Figure 1). As well, direct patient feedback on a number of prosthetic designs with readily available combinations of prosthetic joints and socket materials showed no apparent increase (or decrease) in prosthetic use by amputees.

In 1982, several amputees were again fitted with slightly different combinations of components and sockets. Through the use of questionnaires, speaking to other professionals in the field, and client feedback, a pattern began to develop which identified the areas of greatest concern to the patient. Some of these were as follows: socket discomfort, mobility, weight of prosthesis, insecurity, and energy expenditure.

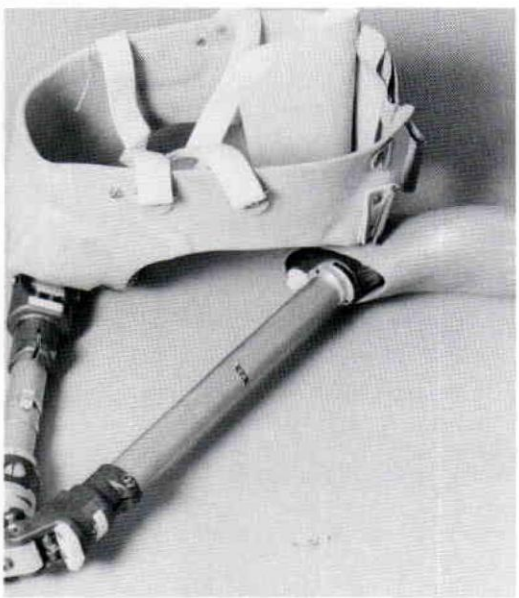

Figure 1. Hip disarticulation prosthesis fabricated in Japan (Yaesu-Labour Corp.) consisting of a diagonal polypropylene socket and knee rotator and adjustable multiaxial foot.

METHODOLOGY

Utilizing the rehabilitation engineering gait laboratory of the Royal Ottawa Regional Rehabilitation Centre, angle-time diagrams from hip, knee, and ankle joints were recorded by electrogoniometers; graphs were plotted by a PDP11 computer to focus on such concerns as mobility, speed, and energy expenditure. The same was done for step length, force displacement, and weight distribution as recorded by a force platform. A split image video recording projected the patient simultaneously from a lateral aspect as well as from an anterior or posterior view. This latter feature was extremely helpful in analyzing the various stages of the gait cycle, as the recording could be replayed frame by frame.

The amputee also found viewing the video tapes helpful in understanding why he/she walked in a certain fashion. Once taught how to correct these gait faults, the individual did so quite readily. By cross examining both video recordings and computer graphs, the prosthetist was able to align the prosthesis more accurately.

The amount of energy expenditure required to walk (at a standard walking rate) while wearing different prostheses can be measured by an oxygen consumption analyzer. By measuring energy expenditure, it has been observed which type of prosthesis requires the least oxygen consumption. This observation should affect future prosthetic designs.

AREAS OF CONCERN

- *Socket Discomfort*

The location of greatest pressure is usually on the ischial tuberosity where most of the weight is borne, both in walking and sitting. Most conventional sockets with rigid or semi-rigid polyester laminations or thermoplastics are only slightly padded with felt, PELITE or leather in this area. In some cases, weight was borne in the symphysis pubis area which resulted in an abducted gait and awkward sitting positions (Figure 2).

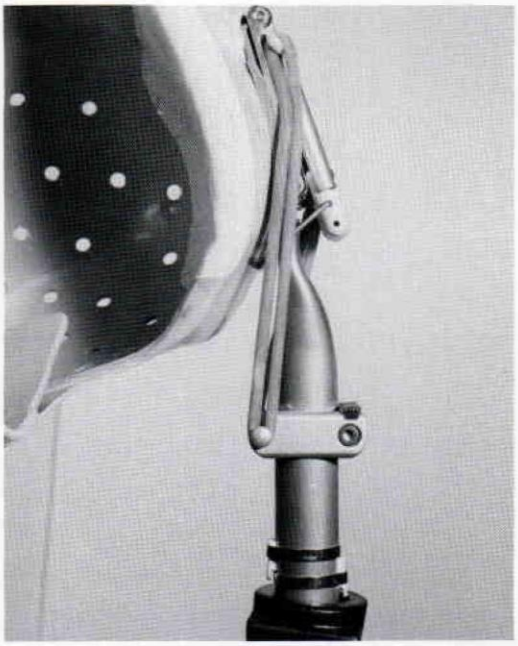

Figure 2. Standard Otto Bock design with 7E4 hip joint, semirigid acrylic laminated socket, showing significant distance between the ischial tuberosity and the bottom of hip joint mechanism.

Patients complained of skin breakdown, heat rashes and general discomfort. They also complained of problems from the proximal socket rim which tended to dig into the lower ribs during sitting and bending, usually leaving large bruises.

Some of these complaints were overcome by using rubberized sockets fabricated from various commercial RTV silicone rubbers, e.g., IPOCON* or ORTHOSIL*. Some custom socket changes to create different weight-bearing areas i.e., below the iliac crest, proved satisfactory in several cases. Further studies need to be done to fully assess the advantages and disadvantages of the use of these materials (Figures 3 and 4).

- *Mobility*

Lack of mobility can lead to painful and embarrassing situations. Most patients complained of the necessity of thoroughly

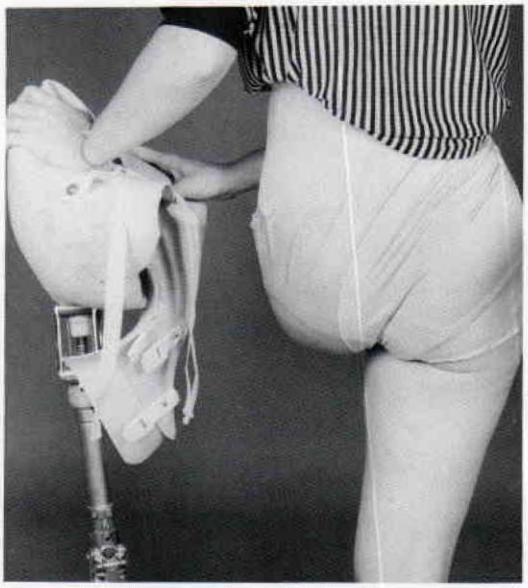

Figure 3. Silicone socket indicating the amount of flexibility.

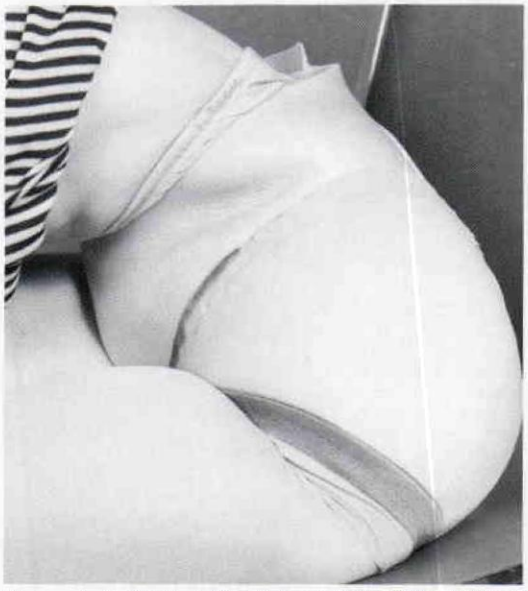

Figure 4. Indicating the deformation of the rubber socket in extreme trunk bending position.

planning ahead, once away from their familiar home or working environment. Within the area of mobility, two concerns arise for the amputee—velocity and maneuverability.

Most amputees are quite adept at crutch walking and can cover a larger distance in a shorter period of time on crutches than by walking with their prostheses. In a number of cases, to encourage prosthesis use, special hip and knee extension assists were used to increase the velocity of walking. However, new but undesirable elements were brought into play by these adaptations. These additional features were eventually rejected by all patients (Figure 4).

Maneuverability is a daily problem encountered by hip disarticulation patients on a large scale. Some of these problems lie in the type of terrain covered, lack of space to maneuver, and the motion of sitting and standing.

- *Weight of Prosthesis*

The average weight of the hip disarticulation prosthesis varies from four to nine kilograms—depending on the additional optional extras in the prosthesis—which is generally deemed acceptable. The use of torque absorbers, 4-bar linkage hip and knee joints, and multi-axial feet all add significantly to the overall weight. The selection of lighter materials for the components as well as for the socket is of great importance.

- *Insecurity*

The fear of falling unexpectedly is a great concern to most hip disarticulation amputees. Despite the use of mechanically sophisticated hip and knee joints, using self-locking and braking mechanisms, extension assists propelled by springs, pneumatic or hydraulic cylinders, insecurity still remains with the patient. The use of more than one prosthetic foot with various heel heights and/or the use of a T-handled Allen key can alleviate the problem of maintaining proper alignment to a certain extent, when changing heel heights of footwear.

Testing the stronger muscle groups in the pelvic region has produced good myosites to explore the possibility of voluntary joint control in the hip and knee joints. Investigations by various researchers are

Figure 5. Otto Bock 7E4 hip joint with hip flexion bias system (HFB) added for initiating hip flexion.

dealing with this issue. Presently, no motor-drive units or other safety mechanisms are commercially available for us to test this feature at the present time.

- *Cosmesis*

Cosmesis plays just as important a role as the mechanics of the prosthesis. Most endoskeletal prostheses offer a much better cosmetic appearance than exoskeletal designs. However, there are still some drawbacks with both designs. The socket area enveloping the entire pelvis adds significantly to the hip and waist circumference. The distortion of the hip area from standing to sitting should also be considered in redesigning the total shape. The appearance of the sitting position was also improved by levelling the pelvis through the use of two new hip joints (See Figures 5 and 6). Most of our test patients were either fitted with the Otto Bock 7B7 or 3R21 joint. Undesirable noises produced by some joints as well as foam covers are presently under investigation.

Figure 6. Otto Bock components: 7E7 hip joint, SR20 knee joint and Teh Lin multi-axial foot.

TECHNICAL INFORMATION ON PRESENT DESIGNS

In the early stages of the project, our main concern was to make the socket as light and thin as possible using 100 percent flexible acrylic resins with lay ups consisting of perlon, nylglass and fiberglass reinforced tricot as well as fiberglass matte. These sockets were up to 50 percent lighter as compared to those done by the standard methods of fabrication. However, the patients did not give any definitive response as to whether this actually produced any advantages.

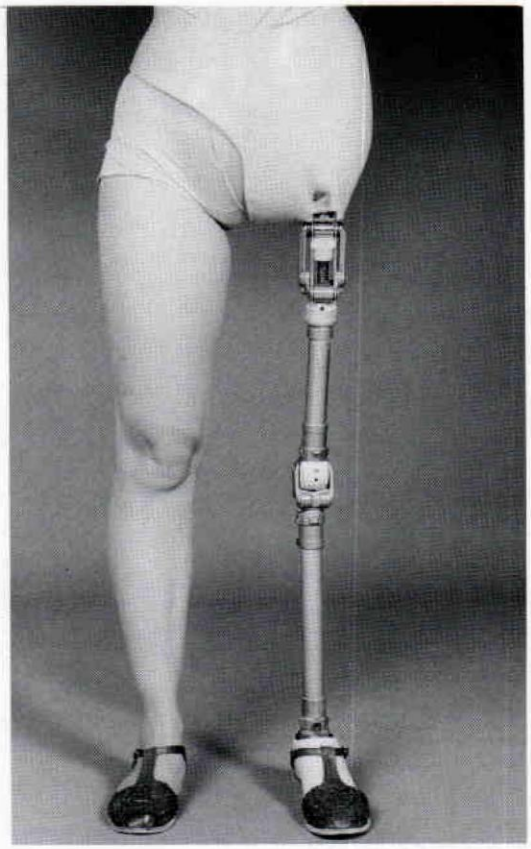

Figure 7. Otto Bock components: 3R21 hip joint, 3R20 knee joint and 4R39 torque absorber, with a 1A13 Greissinger foot.

The next stage was the incorporation of silicone gel pads on top of or in between the plastic laminations. Some felt somewhat more comfortable, but the slight elevation in sitting proved an additional negative factor. Thermoplastic sockets made of surlyn and polypropylene were also attempted, but without conclusive evidence that we were on the "right track." It was not until I received a letter with photographs from Dr. Hannes Schmidl in Bologna, Italy, that we seriously considered fabricating rubberized sockets. The standard Dow Corning #3110 was initially used in doing a 3-part lamination.

First, we did the "inner" socket with six layers of perlon stockinette; then a partial rigid acrylic with fiberglass and perlon lamination incorporating the hip joint hardware. Finally, the third lamination was done similarly to the first one. An anterior opening with an internally "built in" tongue was obtained. However, after only a short trial period, the separate laminations became detached from each other. Several other combinations were attempted, since the initial patient feedback on the rubberized sockets was extremely encouraging.

Our present design is done in two parts (Figure 7). The first one, in six layers of perlon and carbon fiber containing the hip joint hardware, is done over a PVA bag under which are six layers of perlon stockinette next to the cast.

This lamination is trimmed to the appropriate size and shape and replaced on the mold in between the first and second layer of six perlon stockinettes. The rigid plate is previously coated with silicone adhesive which is allowed to cure for two hours.

The second lamination is done with IPOCON rubber using a posterior opening. The location and size of the tongue is very critical. Instead of using Velcro® type fasteners, we use three Fixlock† clasps with webbing fastened to the socket with plastic rivets (Figure 8).

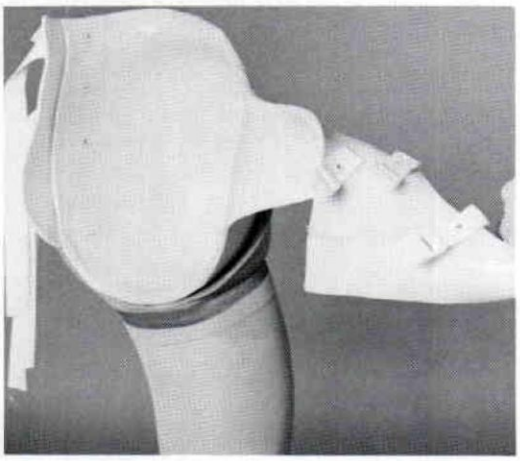

Figure 8. Finished prosthesis with silicone rubber socket and "Fix-Lock" fasteners.

Several other room temperature vulcanizing materials have been tried, including Orthosil, which proved too "floppy" and heavy for our needs.

The initial advantages of the rubber were:

1. Increased freedom of movement in all directions without increasing instability.
2. Increased total contact in sitting, standing or lying down, giving the patient more overall comfort.
3. Increased suspension through the high friction coefficient of the rubberized inner surface.

The initial disadvantages of the rubber were:

1. Increased overall weight of the prosthesis.
2. Increased heat retention, causing perspiration.
3. Clothes sticking to the outer surface of the socket.
4. Difficulty in making alterations or doing repairs.

SUMMARY

These independent findings form a basis for further investigation into priorities for the redesign of hip disarticulation prostheses in which the wearing of the limb will be optimized and normalized (Figure 9).

I want to give a special word of thanks to the many colleagues who have participated in sending information, in most cases not published yet, on their own recent attempts to improve the hip disarticulation prosthesis. A special thank you to Mr. B. Wester and Mr. P. Tiul whose article dealt with pure speculation, which in our estimation has proven to be very helpful in proving that a knee joint can be successfully used as a hip joint.

Some of the patients referred to us were initially fitted outside our geographical area. Once they had returned home, they were referred back to their original prosthetists, to whom we sent as much information as possible to help them become familiar with their patient's new prostheses.

Figure 9. Increased comfort is achieved in walking as well as in sitting.

It is anticipated that at the end of 1985 a "hands-on" seminar will be organized to invite as many interested prosthetists (and patients) to participate in an information exchange clinic in Ottawa. This study is still in its infancy and the author intends to publish updates at regular intervals to keep the prosthetic field informed.

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*IPOCON—product of IPOS, distributed by W.H. Hood Co., Victoria, Ontario. ORTHOSIL—product of Otto Bock Orthpaedic Ind. and Serum International.

†"Fixlock," made in Sweden, is distributed by Spae Naur Products, Kitchener, Ont. or, in the U.S.A. by Therapeutic Recreation Systems, Boulder, Colorado.

Orthotics and Prosthetics, Volume 38, Number 1, Spring, 1984, pp. 36–44.

The Thoracic Suspension Jacket— Review of Principles and Fabrication

Carlton E. Fillauer, C.P.O.
Charles H. Pritham, C.P.O.

Apparently, the first reference to the Thoracic Suspension Jacket was in an article by Siebens[1] in 1972. Since then, considerable experience with it has been amassed at Newington Children's Hospital and other localities as described by Siegfried Paul, C.P.O., (E), [2,3] James C. Drennan, M.D.[4,5,6] and others. Durr-Fillaur's involvement began in 1974, and over the years, simplified fabrication procedures using prefabricated components adaptable to wheelchair use or other sitting accommodations have been developed.

There have been frequent requests from orthotists for information relating to it. It is hoped that this article will at least partially fulfill the need.

DESCRIPTION

The Thoracic Suspension Jacket is a custom molded Thoraco-Lumbo Sacral Orthosis with an anterior opening and a PELITE* lining. The portions under the antero-lateral aspect of the costal margins are indented to provide shelves on which the ribs rest and the inferior edge is trimmed higher than usual for sitting comfort. Suspension lugs are secured to the right and left sides of the jacket and hangers are secured to the back uprights of the wheelchair on which the jacket is suspended. Adjusting the height of the hangers and clamps permits the amount of weight borne by the thorax to be increased or decreased. By this means, the distractive effect of the lower portion of the body can be used to extend the spine and/or the buttocks, and other pressure sensitive areas can be relieved of superincumbent weight.

INDICATIONS AND CONTRAINDICATIONS

Drennan[4,5] has described the orthosis as being indicated for individuals with paralytic spinal deformity for whom surgery, for whatever reason, (immature skeletal growth, life threatening complications, etc.) is not contemplated. He has described the objectives as:

- arrest or correction of spinal deformity
- improvement of sitting balance
- freeing of the arms from the role of trunk supports
- improved appearance and body language
- increased independence and mobility

- improvement of respiratory function
- relief of pressure and decubiti over the ischial tuberosities and sacrum
- relief of back pain

He cited prerequisites to success as being:

- willing patient and family cooperation
- presence of a skilled and experienced team including orthotist, physician, therapists, and nursing staff

Surprisingly enough, Drennan stated that anesthetic skin, with appropriate attention to detail and follow up, had not been a problem and that patients without sensation had developed tolerances of up to 10-12 hours. While adequate hip flexion for sitting is essential, it was found that fixed pelvic obliquities and dislocated hips could be accommodated.

Relative contraindications creating problems (and in some case failure) were listed as:

1. uncooperative family and patients.
2. hip joint stiffness with inability to sit.
3. severe athetoid cerebral palsy or severe involuntary movements.
4. gross obesity, as the underlying structures are difficult to grasp and the load imposed may be more than the skin can tolerate.
5. Cachexia (condition of general wasting marked by extreme thinness and muscular atrophy). Patients tended to "slip through" the orthosis, especially those with muscular diseases and progressive weight loss and atrophy.

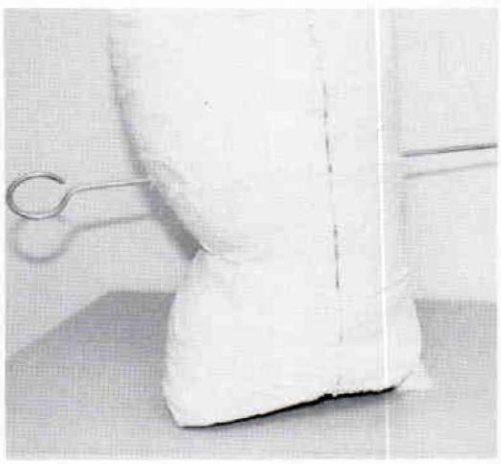


Figure 1. Cast with casting rod in place, posterior view.

In a similar vein, Robin Black[7] has listed as complicating factors:

1. severe spinal deformity leading to unequal loading on the rib cage and reduced tolerance time.
2. obese individuals.
3. patients with ileostomies.
4. poorly motivated patients.

FABRICATION

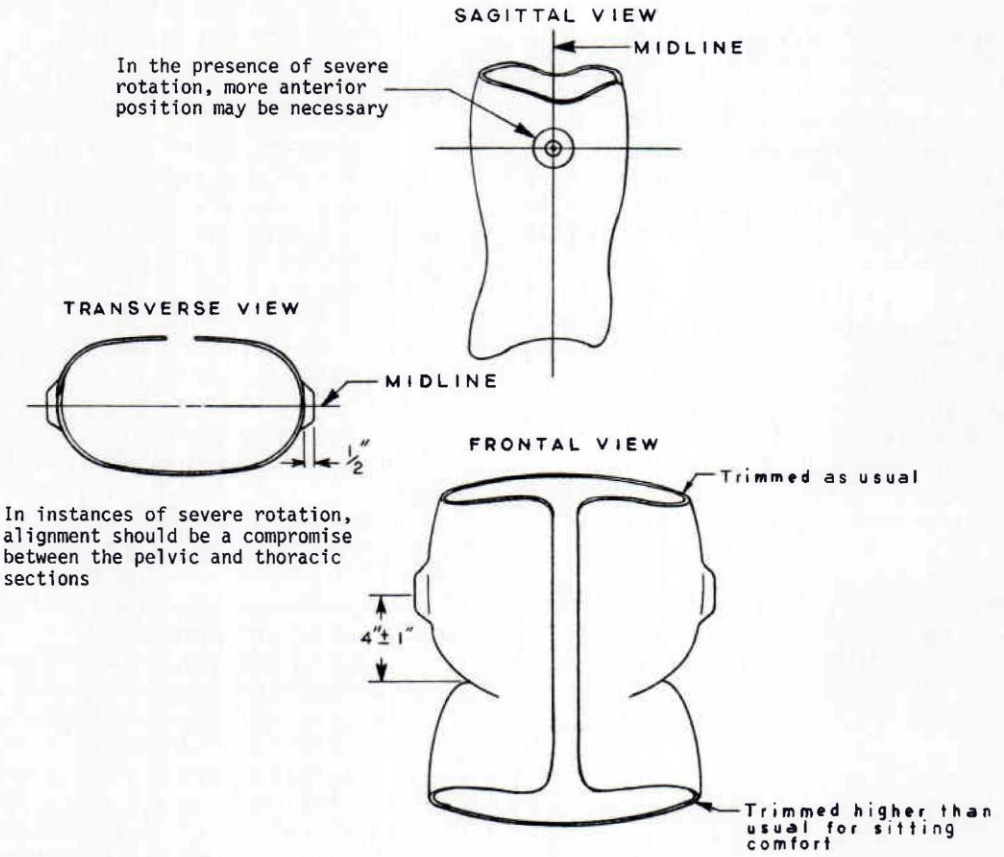
The negative impression is made in the usual fashion. The patient mey either be positioned supine on a Risser table and wrapped circumferentially or positioned prone on the end of an ordinary fitting table with the knees flexed for casting in two steps with splints. In this latter instance, use of the Durr-Fillauer Pelvic Casting Fixture may prove helpful. Whatever technique is used, flexible curves should be corrected, and the space superior to the iliac crests and inferior to the costal margins should be indented in the usual manner. Before removal of the negative impression, the patient should be positioned straight, keeping in mind the eventual sitting posture, and anterior and lateral center lines drawn.

Following removal of the negative impression from the patient and closure, the suspension points are identified as depicted in Table 1. While the method of clamping the hanger rods to the wheelchair gives considerable adjustability, the suspension points should be located as accurately as possible, taking into account such things as decompensated curves and eventual sitting position. Once the suspension points are located, ¼" holes are cut in the negative impression and the lubricated casting rod is positioned in them (Figures 1, 2). The negative impression is poured in the usual fashion, the rod is then removed (leaving a clear channel through the positive model), and the cast is removed from the positive model.

The positive model is smoothed and modified in the usual manner. Drennan[4]

TABLE I

LOCATION OF SUSPENSION LUGS



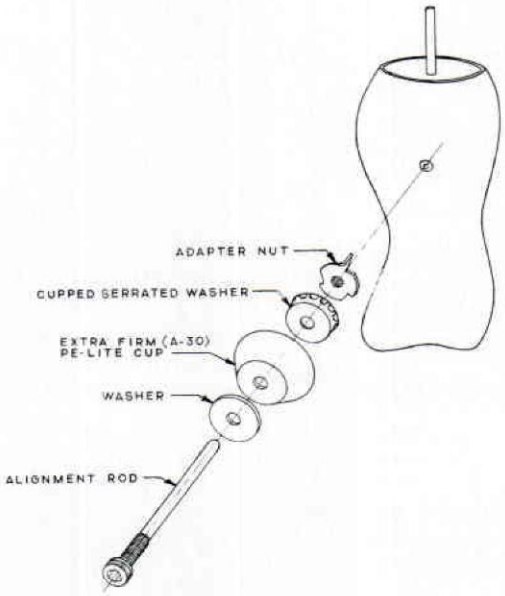
has recommended building up the areas superior to the costal margins to give room for chest expansion and respiration. Similarly, he has advised removal of plaster in the upper abdominal area to provide hydraulic resistance to contraction of the diaphragm and thus again aid chest expansion and respiration.

The modified positive model is prepared for vacuum forming and covered with a layer of 5mm A8 ventilated medium density PE-LITE (Figure 3) with an anterior opening. For several years the suspension lugs were mounted on anchor cups fabricated of aluminum and rigid polyurethane foam. Recently a quicker and more efficient means of mounting the suspension lugs has been devised.

The PE-LITE cup, adapter nut, and the rest of the components of the lug mount are assembled on the alignment rod as shown in Table 2.

TABLE II

EXPLODED VIEW OF ALIGNMENT ROD AND LUG MOUNT COMPONENTS



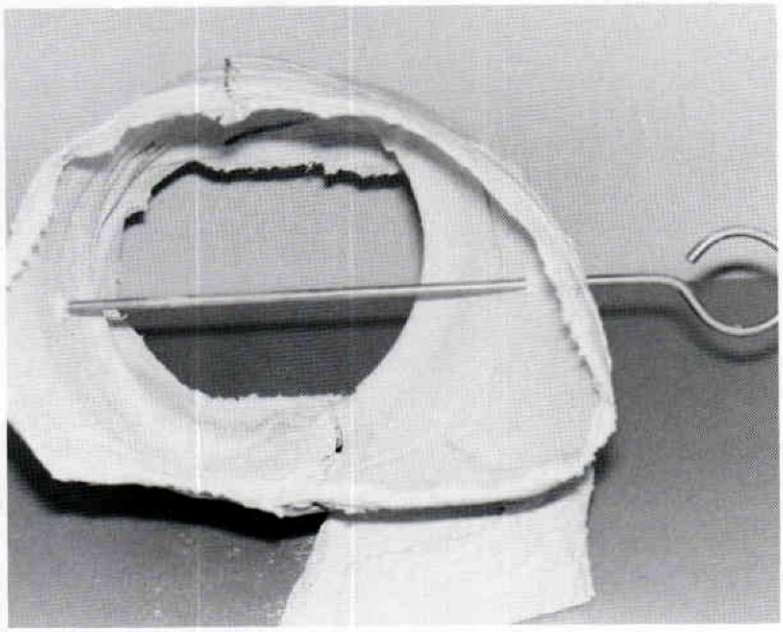


Figure 2. Inside view of cast and casting rod.

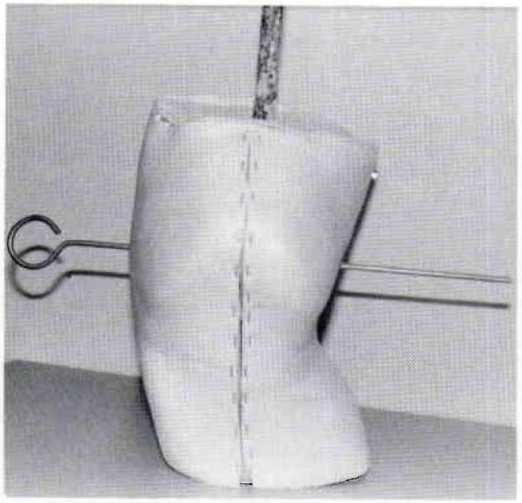


Figure 3. Anterior view of model with PELITE and casting rod in place.

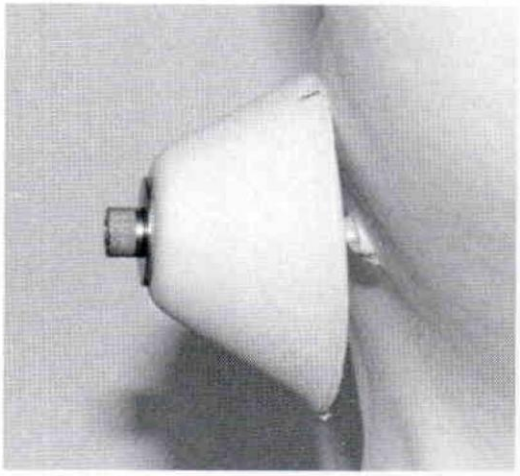


Figure 4. Lug mount assembly and alignment rod inserted in hole in model.

The alignment rod is inserted in the hole previously provided by the casting rod (Figure 4) and the amount of PE-LITE to be removed is identified by measurement (Figure 5).

The PE-LITE cup is trimmed so that it makes even contact with the surface of the positive model and protrudes no more than 1/2". When properly contoured, the PE-LITE cup (Figures 6, 7) is filled with Rapid-cure† and repositioned on the positive model in proper alignment (Figure 8). Once the acrylic compound reaches a stiff dough-like consistency, it is faired into the surface of the PE-LITE using a fingertip dipped in the methylmethacrylate catalyst. Once the lug mounts are properly shaped and secured in place, the alignment rod is removed (Figure 9) and the positive model is vacuum formed with 3/16" polyethylene.

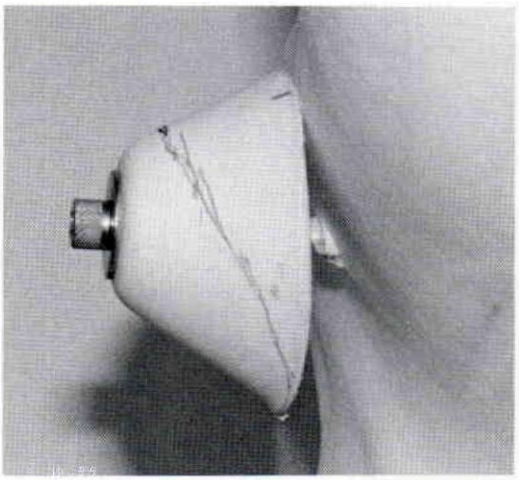


Figure 5. Amount of material to be removed is measured and marked.

When the polyethylene has cooled, the threaded holes in the lug mounts are exposed using a 3/8" drill (Figure 10) and a 5/16"-18 tap is used to clear the threads and properly align the hole (Figure 11) in the polyethylene.

The areas about the holes are heated (Figure 12) and the suspension lugs securely screwed into position (Figure 13) so that the plastic forms flat seats about them. Trimlines are drawn on the orthosis (Figure 14) and it is removed from the positive model and finished as usual.

The clamp assemblies and hanger rods are secured to the chair horizontally (Figures 15, 16, 17) to provide appropriate positioning of the orthosis in the wheelchair. While rotation of the clamp assemblies on the uprights of the wheelchair provides considerable adjustability, modification of the hanger rods may be necessary. Although the thoracic suspension orthosis is generally adjusted so as to relieve the buttocks of the patient's

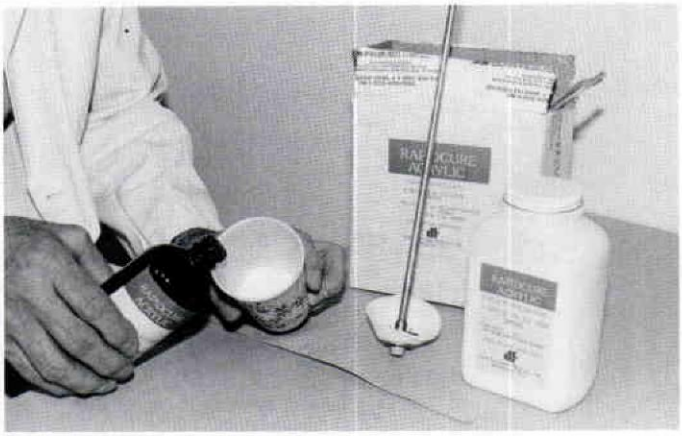


Figure 6. (Left) Mixing methylmetacrylate to fill the PELITE cup.

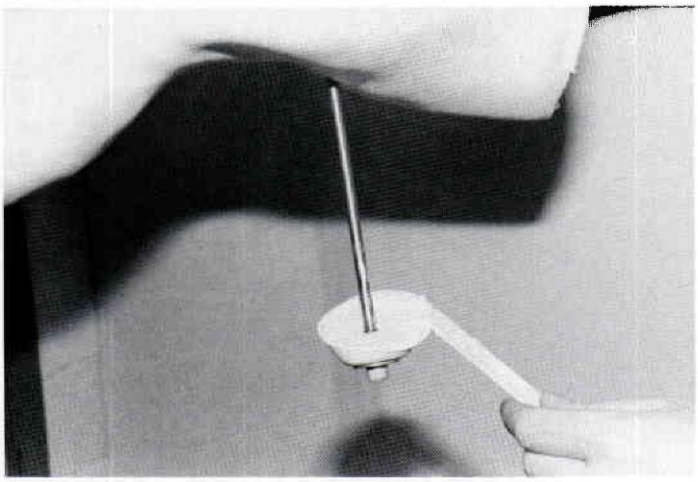


Figure 7. (Right) Cup filled with Rapidcure. Model has been positioned upside down in pipe vise.

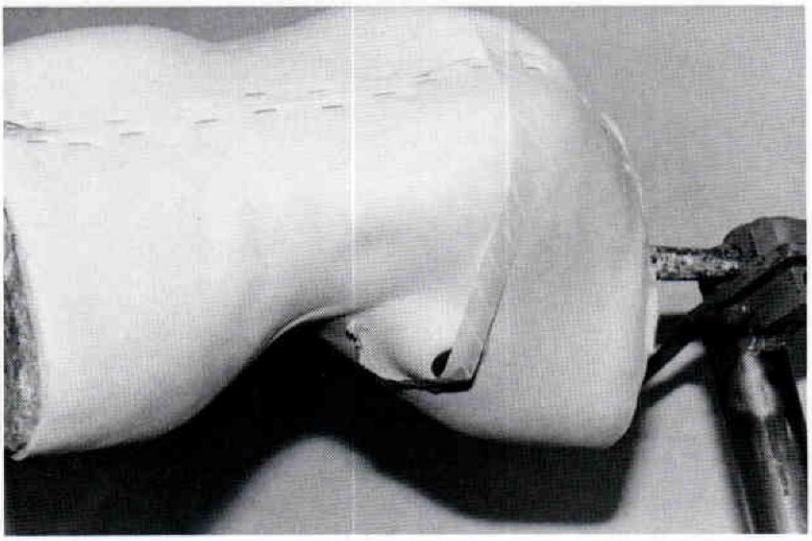


Figure 8. (Left) PELITE cup held in place until the methylmetacrylate sets.

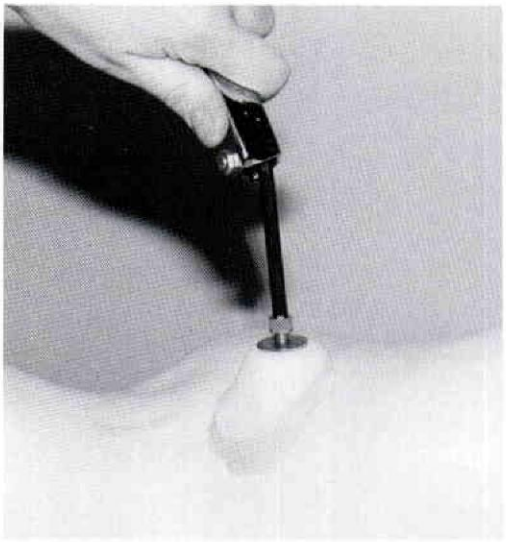


Figure 9. The alignment rod is removed from the lug mount after the edges are faired into the contours of the model.

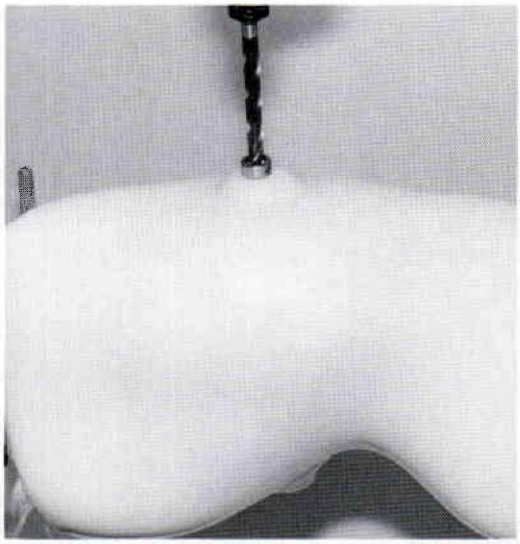


Figure 10. Drill used to open up the holes in the polyethylene over the lug mounts.

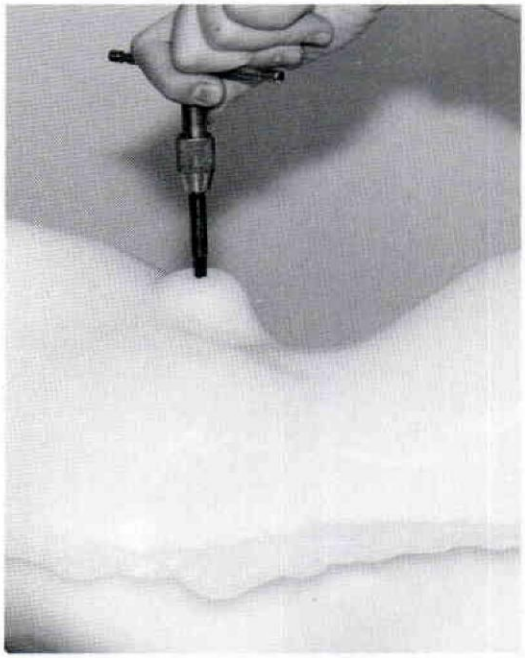


Figure 11. A tap is used to clear the threads and align the holes.

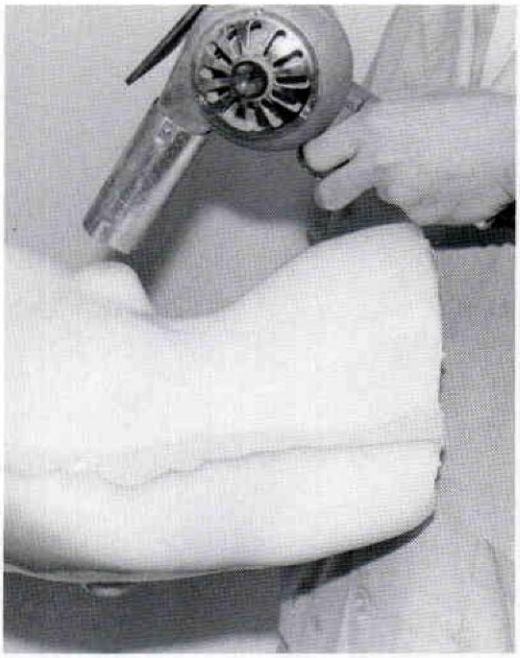


Figure 12. Heating the areas about the holes.

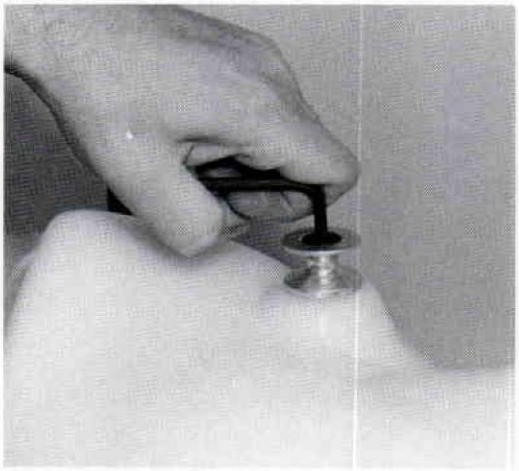


Figure 13. Securing the suspension lugs in place while the polyethylene is soft.

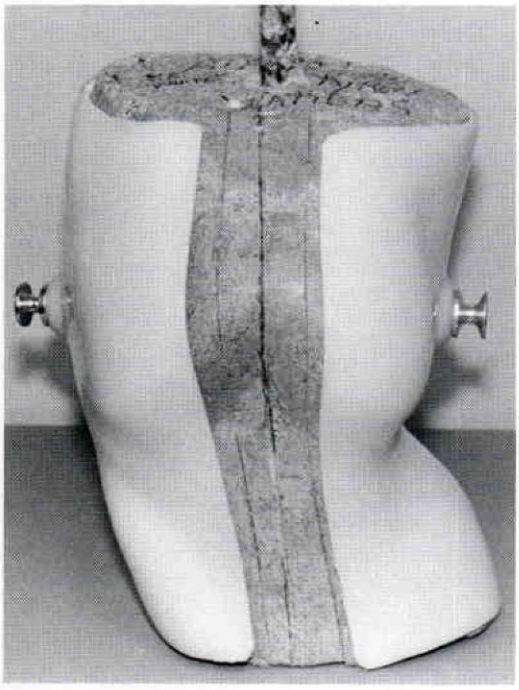


Figure 14. Orthosis with suspension lugs secured in place and initial trimlines cut and smoothed.

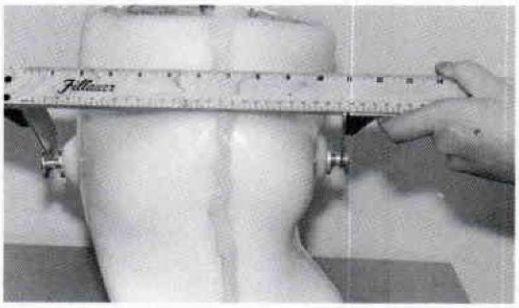


Figure 15. The distances between the two suspension lugs is measured.

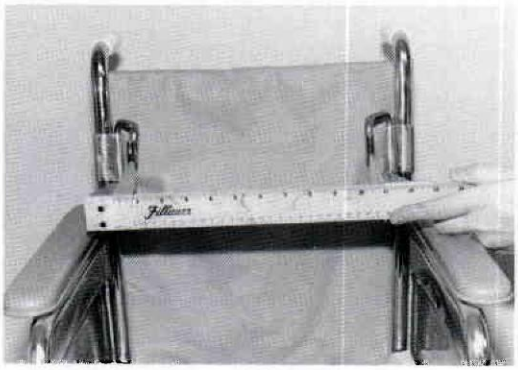


Figure 16. With that measurement as a guide, the clasp assemblies are installed on the chair.

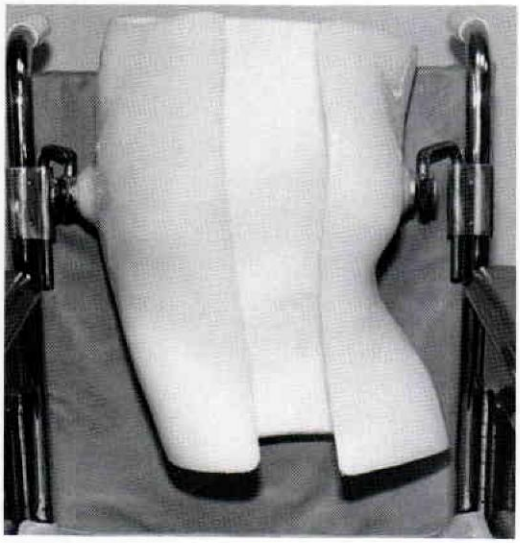


Figure 17. Finished orthosis mounted on the chair.

weight, it may also be used for stabilization of the torso without weight-bearing.

BREAK-IN PERIOD AND FOLLOW UP

Drennan and Black[4,5,6,7] agree that wearing tolerance should be built up very gradually over a period of several weeks. The goal is that in 2-3 weeks time, the patient can use it for a full day with periods of relief from suspension. Drennan recommends hospitalization for this period of tolerance building and discharge once the patient can tolerate suspension for two hours out of four. Obviously, success depends on willing, intelligent cooperation of the patient and family.

The orthosis should be used daily to maintain tolerance, the skin should be inspected daily, and care should be taken to avoid wrinkles in undergarments worn. Areas of redness that do not clear after 20 minutes should be brought to the attention of the orthotist for appropriate action. Patients should not be transported in suspension, as the jarring motion can cause discomfort and skin breakdown. Drennan[4,5] has reported that new orthoses were necessary on the average of 15 months after initial fitting, with a readmission to the hospital of about three days.

RESULTS

In 1979, Drennan[4] reported the results of 62 patients fit since 1972. The suspension orthosis was prescribed most frequently for spina bifida, cerebral palsy, Duchenne muscular dystrophy, spinal muscular atrophy, trauma, and various other conditions. Patients ranged in age from 14 months to 26 years. Five instances of failure were described and attributed to: lack of cooperation, obesity, hip joint stiffness, severe athetoid cerebral palsy, and extreme and progressive cachexia.

Similarly in 1975, Robin Black[7] described the results of fitting over a dozen children with spina bifida with suspension jackets over a period of two and one half years. Eight patients were identified as having benefited from use of the jacket, five of them remaining free of pressure sores for more than one year.

In addition, Karl Fillauer, CPO has fitted several patients with hemicorporectomy amputations with suspension orthoses and achieved good results.

CONCLUSION

The Thoracic Suspension Jacket has proven itself to be an efficient and practical means of handling individuals with severe scoliosis and decubitus ulcers. For the benefit of those who may not be familiar with the orthosis, indications, contraindications, fabrication, and follow up procedures are reviewed. It is hoped that this information will be of some assistance in meeting the needs of the severely deformed.

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AUTHORS

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*A closed cell Polyethylene foam

†Rapidcure, a methylmethacrylate plastic, is a product of Durr-Fillauer Orthopedic Division.

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A New Design and Construction For a Swimming Prosthesis

Carlo Marano, C.P.
Eugene DeMarco, C.P.

This article, which concerns an innovation in ambulation for the active amputee, may be read in conjunction with the article by Kenneth P. LaBlanc, B.S., C.P.O., in Orthotics and Prosthetics, *Vol. 37, No. 3, pp. 42-49, "Fabrication of the Water Resistant B/K Prosthesis."*
The Editors

The ability of the lower limb amputee to participate in recreational activities is sometimes necessary in order to improve the quality of his or her life. Swimming, in particular, can be an enjoyable method of exercise for the amputee.

Prosthetic devices for swimming are necessary, not only to improve one's ability to swim, but to provide:

- a safe means for ambulation in and out of water
- protection against trauma to the residual limb
- constancy of residual limb volume during swimming activities
- safety in the shower.

Contemporary prosthetic devices for swimming satisfy the latter objectives, but fall short of providing maximum safety. Especially when ambulating in water, problems have been encountered due to the buoyancy of these devices. A prosthesis that is fully buoyant may be hazardous to the wearer. A great amount of effort must be exerted to keep the prosthesis submerged. A reduction in buoyancy gives the patient a greater degree of control over the prosthesis. He can affect its position with a degree of coordination and muscle power that more closely approximates out-of-water ambulation.

When a body is immersed in a fluid, it is buoyed up with a force equal to the weight of the fluid displaced by the body. Therefore, in order to reduce the buoyancy of a swimming prosthesis, one must reduce the amount of water that it displaces.

It was our goal to design a swimming prosthesis that was practical, cosmetic, safe, and displayed a minimal amount of buoyancy. We have achieved this end by constructing a prosthesis with a large central chamber through which water can enter and exit quickly.

This chamber has a distal opening located in the base of the water repellent foot, and a proximal opening in the posterior shelf of the socket (Figure 1).

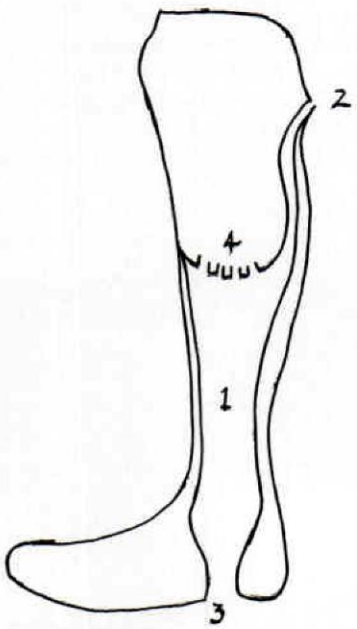

Figure 1. Schematic drawing of swimming prosthesis: (1) central chamber, (2) proximal opening, (3) distal opening, and (4) distal socket drain.

As the amputee enters the water with the prosthesis, water enters the distal opening and begins to fill the chamber. Air is simultaneously expelled through the proximal opening. The water level in the chamber will equilibrate with the water level outside the prosthesis until the prosthesis is completely submerged. As the prosthesis is removed from the water, air enters the proximal opening and forces water out distally. Without this proximal opening, the amputee would feel a downward pull on the prosthesis due to the force of the exiting water.

THE WATER REPELLENT FOOT

The distal opening of the central chamber is a 1.25 inch diameter hole in the base of a specially prepared foot. Experience has demonstrated that water, especially salt water, readily deteriorates the foot portion of a swimming prosthesis as well as its attachment to the shank. Efforts to reduce maintenance and facilitate fabrication, without reducing function, have led to the design of a water repellent foot for swimming prostheses.

The keel of the foot is fabricated from 350 grams of Pedilen foam (three parts hard to one part soft) poured into a neuter blank mold. This blank can be shaped to accommodate all foot sizes, left and right (Figure 2).

Otto Bock Pedilen toe and sole parts are chosen to correspond to the patient's foot size and fitted to a flat rubber swimming sneaker. The keel is shaped to fit these components.

Fiberglass cloth, impregnated with polyester resin, is sandwiched between the base of the keel and the plantar components of the foot. This layer insures a strong keel base and an intimate fit with the sole of the foot.

THE BELOW KNEE SOCKET

All below the knee swimming prostheses fabricated in our laboratory utilize PTB sockets with Supracondylar or Supracondylar/Suprapatellar suspension systems. These have proven to be the suspension types of choice. Auxiliary suspensions should be avoided whenever possible, because immersion in water increases their rate of deterioration and thus affects safety and frequency of repair.

As previously stated, the water emission rate from the central chamber can be increased by providing a proximal opening in the posterior brim of the socket (Figure 3). This opening is created during the socket lamination. A 1.5 inch wide, slightly tapered, piece of .125 inch thick polyethylene is inserted between the layers of stockinette prior to lamination. The polyethylene wedge extends to the distal end of the socket but is easily removed by heating the posterior aspect of the socket. When the tapered wedge is removed, it will leave a channel that will ultimately drain into the central chamber of the shank.

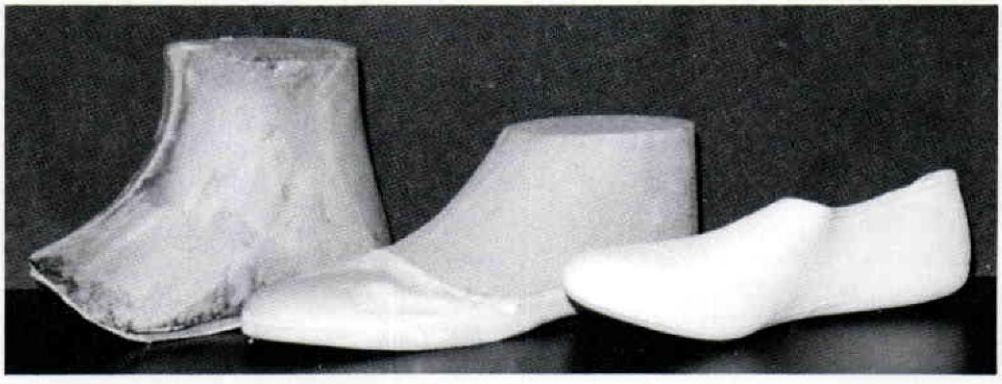

Figure 2. Components of "water repellent" foot: (left to right) neuter blank mold for urethane keel; shaped keel attached to Pedilen foot parts; swim sneaker.

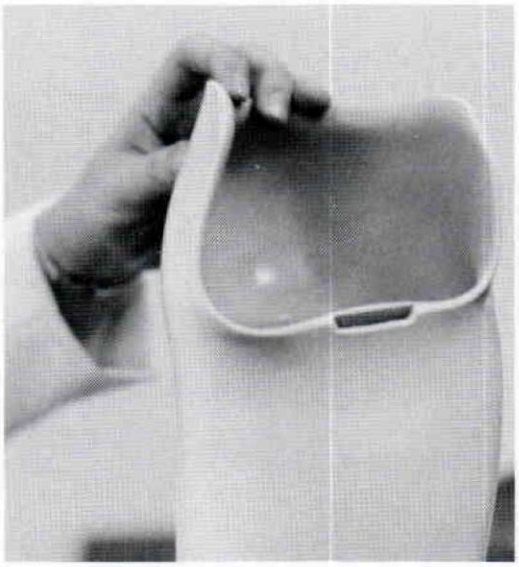

Figure 3. Posterior socket channel in proximal brim—air passes through this opening to facilitate equilibration of water level.

Figure 4. Distal socket drain leads to the central chamber of the shank and allows water to enter the socket.

Additional openings to the chamber are produced by drilling .125 inch diameter holes through the distal end of the socket (Figure 4). The final result is a socket in which the posterior channel and distal openings empty into the central chamber of the shank. Air pressure through these openings increases the rate of water flow in and out of the prosthesis.

ALIGNMENT AND FITTINGS

The socket is embedded in urethane foam and is attached to an adjustable pylon. The foot is attached to the pylon using a wooden block as a base for the foot plug (Figure 5). All alignment procedures are performed according to established techniques.

Since the swimming foot has no compressible SACH component, the patient may experience increased flexion at heel strike. It may be necessary to bevel the posterior aspect of the heel, to a 45 degree angle, to help reduce this moment. The patient will adjust to this slight increase in flexion at heel strike while walking on solid ground. When ambulating on sand, or

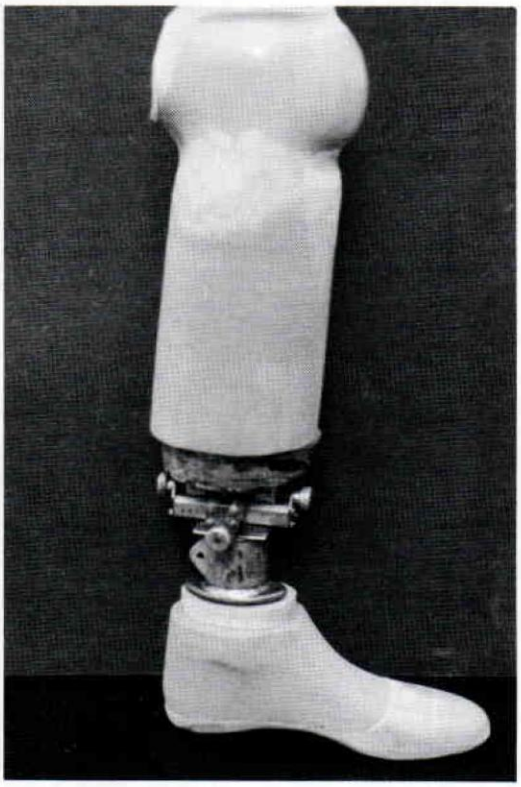

Figure 5. The swimming socket and foot attached to the adjustable pylon are ready for fitting.

other soft terrain, the compression of the sand will provide an even smoother gait pattern.

Alignment duplication is performed using urethane foam as a shank filler. Subsequent to a second dynamic alignment, the prosthesis is shaped and prepared for the finishing process.

FINISHING PROCESS (BELOW KNEE)

After cosmetic shaping, the toe and sole parts are removed and the prosthesis is laminated with polyester resin in two layers of fiberglass stockinette. The prosthesis is then reference marked and cut in a transverse plane at the shank. All the urethane foam within the shank is removed, thus creating the central chamber. The two hollowed sections are glued together and smoothed for final lamination. The final lamination consists of three layers of nylon stockinette saturated with polyester resin and the appropriate pigment.

After final trimming, the Pedilen foot parts are adhered to the base of the keel with epoxy and covered with a swim sneaker. The sneaker is glued to the keel and a 1.25 inch diameter hole is drilled through the sneaker and foot parts (Figure 6). It is this hole that becomes the distal opening of the central chamber. The finished prosthesis is shown in Figure 7.

ABOVE KNEE PROSTHESES

The aforementioned techniques can be incorporated into the fabrication of above knee prostheses.

The knee unit of choice is the Otto Bock 3K5 unit. It is plastic, lightweight, and ideal for immersion in water when the metal extension spring is removed. The openings in the knee eliminate the need for a posterior socket channel.

The foamed socket, knee, and water repellent foot are set in bench alignment and glued. The prosthesis is then fit according to established practice; however, the patient must ambulate with the knee locked.

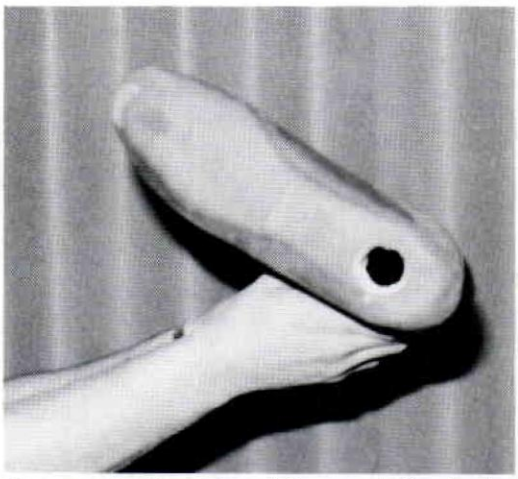

Figure 6. Distal opening of the central chamber located in the base of the foot, allows free flow of water in and out of the chamber.

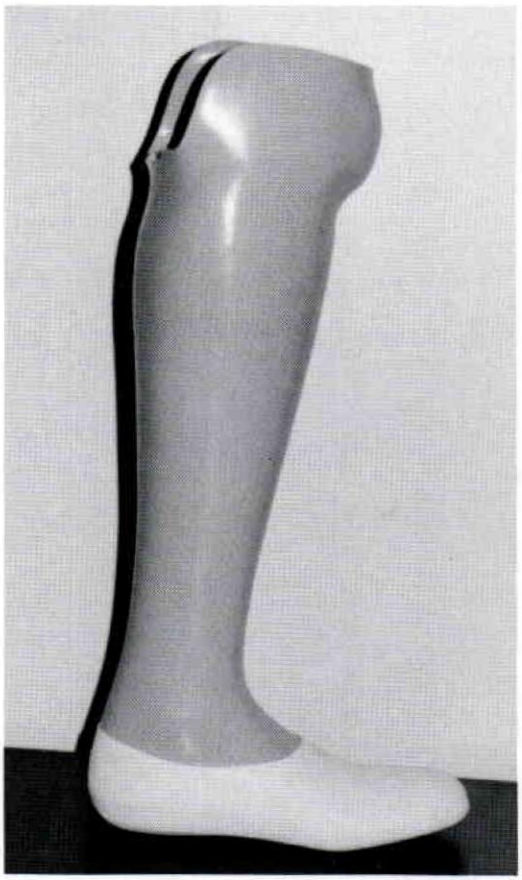

Figure 7. The finished below knee swimming prosthesis.

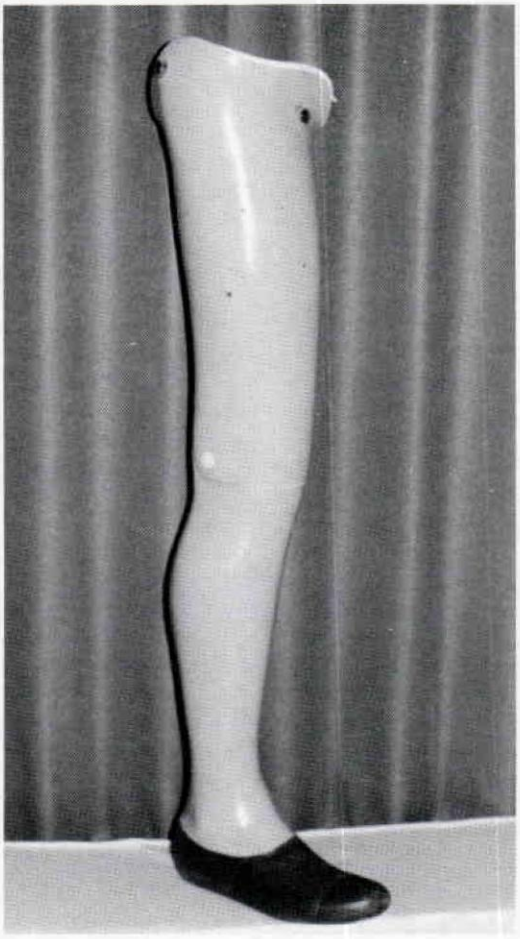

Figure 8. The finished above knee swimming prosthesis.

FINISHING PROCESS (ABOVE KNEE)

After the fitting, the prosthesis is shaped and disassembled. The shank portion is treated as described under the below knee finishing process. It is laminated, cut, hollowed, and relaminated with pigment. The thigh section is hollowed to the distal end of the socket.

Water enters the thigh via the openings in the upper portion of the knee. The openings in the lower portion of the knee are the proximal entry to the distal chamber that is created in the shank.

The foot parts are attached as in the below knee. The swim sneaker is glued to the foot and the distal hole is drilled through the sneaker and foot parts (Figure 8).

DISCUSSION

We have used the techniques outlined for more than twelve years. To date, we have followed the progress of 34 patients wearing swimming prostheses fabricated as described. All the patients were able to achieve their functional goals, from participating in water sports to taking daily showers. The only routine service is an annual check up to insure the integrity of the components.

The patients experience no significant limitations other than a slight decrease in simulated plantar-flexion, but they easily accommodate to it. Above knee patients are limited to walking with the knee locked. Long above knee residual limbs present a cosmetic problem due to the dimensions of the 3K5 unit and the resultant protrusion of the knee.

There are great limitations on the types of components that can be incorporated into a swimming prosthesis. Development of a variety of components, specifically for recreational prostheses, is necessary if we are to help in the rehabilitation of our patients.

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A New Cervical Neck Ring for the Idiopathic Scoliosis C.T.L.S.O.

Greg Moore, R.T. (O)

The Milwaukee orthosis has been used in the treatment of scoliosis since 1946.[1] Originally designed for post-operative spinal management, this orthosis has since developed into one of the best non-operative management methods used to manage the progression of a scoliotic curve (Figure 1). The C.T.L.S.O. has been used successfully in the management of juvenile idiopathic scoliosis, infantile idiopathic scoliosis, congenital scoliosis and kyphosis.

Figure 1. Original Milwaukee Brace, ca. 1945.

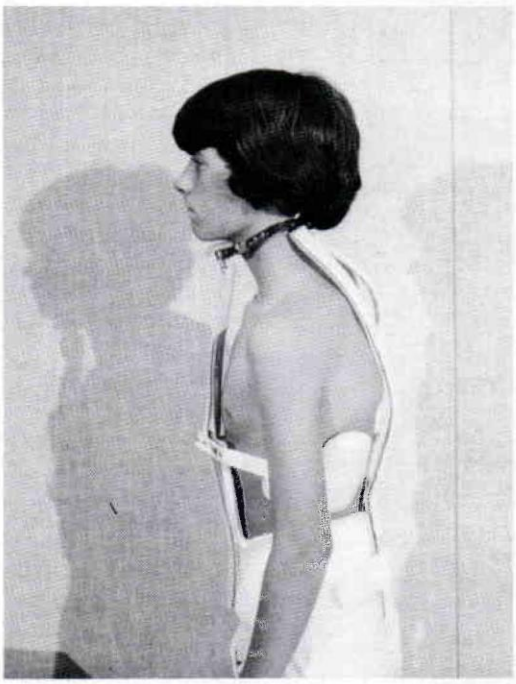

Figure 2. Contemporary Milwaukee.

There have been many improvements to the orthosis since its inception, as new materials and diagnostic procedures have become available to the orthotist. These improvements have helped create an orthosis which, compared to the original

orthosis, is more comfortable, easier to don and doff, easier to clean, and is more cosmetically acceptable to the patient (Figure 2).

SCOLIOSIS POPULATION

The incidence of idiopathic scoliosis as reported in a 1978 study by Rogala[2] was 4.5 percent for a scoliotic curve of more than five degrees and two percent for a curve over ten degrees. Of this population, 6.8 percent exhibited a progression of five degrees or more leading to a range of 20 degrees of curvature or more. Of these, 95 percent were treated with braces, and in all but 2.6 percent, the treatment was successful. From these figures it is probably safe to say that for progressive structural curves of more than 15 degrees, a brace is indicated. Once a curve has reached 40-45 degrees, surgical corrections are likely to be necessary, except in some well-compensated double curves, when up to 60 degrees may be corrected with an orthosis.

RESEARCH AND DEVELOPMENT

Our first attempts to improve the cosmesis of the C.T.L.S.O. neck ring were prompted by Dr. E.E. Bleck, professor and executive head of the Division of Orthopedics, Stanford University School of Medicine, who requested an innovative and highly cosmetic neck ring design which would give lateral control of the cervical region. The original Milwaukee neck ring provided a large longitudinal distraction force which can only be applied at the risk of damage to the growing bones of the mandible and maxilla, creating orthodontic problems. Because of this, the concept of forceful longitudinal distraction has been abandoned and the concept of a three point pressure system, with optional mild mandibular distraction, has been adopted. The use of a lateral three point pressure system, provided by a thoracic pad below the apex of the major curve, resisted by an incapsulating pelvic girdle below and the neck ring above, has proven successful. The use of such optional fitting elements as a lumbar pad to create additional three point pressure has oftentimes proven necessary.

There is no doubt that the management of scoliosis with the C.T.L.S.O. for a period of several years is often emotionally traumatic for a teenager to face. To minimize this, constant efforts must be made to reduce the stress on the patient in terms of weight, function, and cosmesis. Since the majority of patients are adolescent girls, the aesthetic quality of the brace can make a significant difference in the patient's acceptance of the brace. It is in keeping with this effort that our first modified neck ring was constructed (Figure 3).

Figure 3. First modified neck ring.

Designed to fit Durr-Fillauer prefabricated components, the modifications to the neck ring eliminated the entire anterior portion of the conventional throat mold neck ring, including the hinge system. A new hinge system was designed and constructed which, by using the anterior mounting plate as the attachment device and hinge, afforded a more unobtrusive and cosmetic anterior section. This accomplished, the posterior section was modified by removing the upright attachment tabs and attaching the posterior superstructure uprights directly to the posterior segment of the neck ring. Some of the bulk of the neck ring was thus reduced,

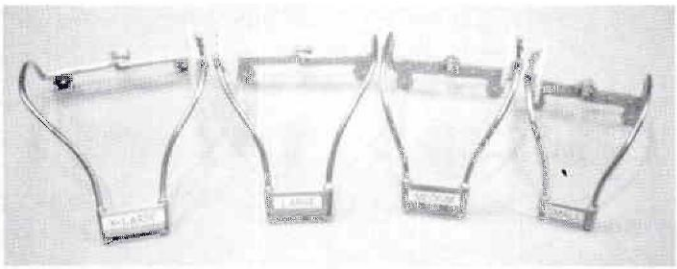

Figure 4. Durr-Fillauer low profile neck ring.

creating a closer fitting and more cosmetic posterior section.

This modified neck ring design was used on eighteen C.T.L.S.O. patients with overwhelming patient, parent, and doctor acceptance. The patients liked the new design so much that three veteran C.T.L.S.O. wearers, having seen the new design, insisted on having their orthoses converted to include the new neck ring.

The time involved in the fabrication of the modified neck ring (averaging four to six hours each) prompted the inquiry to the Durr-Fillauer Company, regarding their consideration in manufacturing the modified neck ring. A prototype neck ring was sent to their new products department, providing the impetus for the second low profile design. This cervical neck ring uses the concept of the combined anterior mounting plate and hinge, and carries the concept one step further by extending the stainless steel rods within close proximity of the lateral borders of the neck, curving over the shoulders to a knurled knob closure in the proximity of the C7 vertebra (Figure 4). This further enhances the cosmesis of the neck ring and keeps the closure away from the posterior inferior hairline, reducing the problem of catching hair

Figure 5-A. Patient in orthosis with low profile neck ring, shirt on.

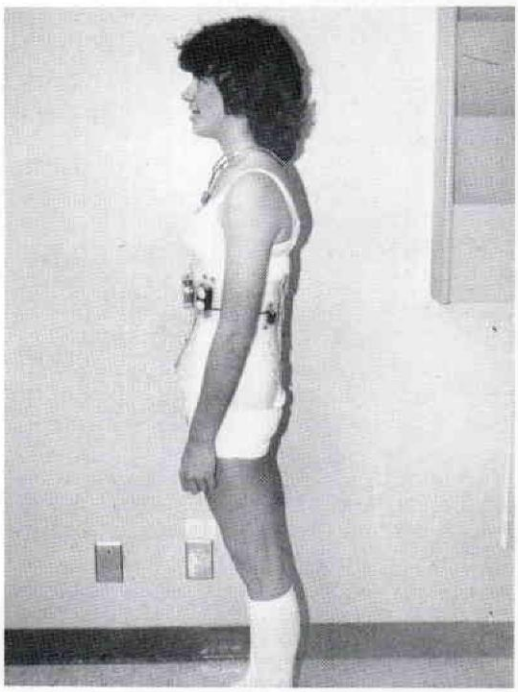

Figure 5-B. Patient in orthosis with low profile neck ring, shirt off.

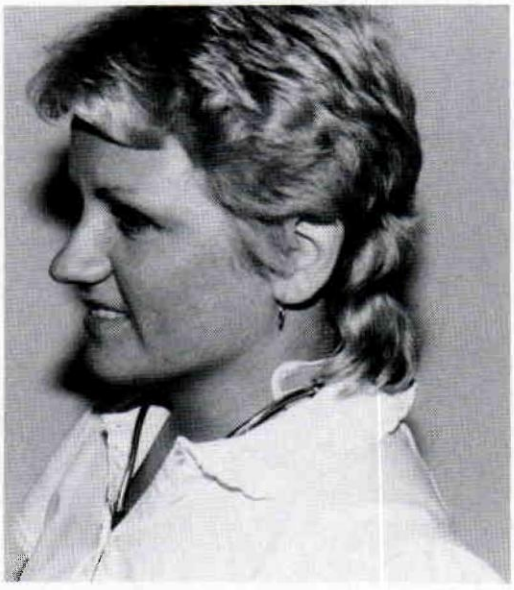

Figure 6. Close-up showing lateral pad.

Figure 7. Close-up of patient with low profile neck ring and mandibular support.

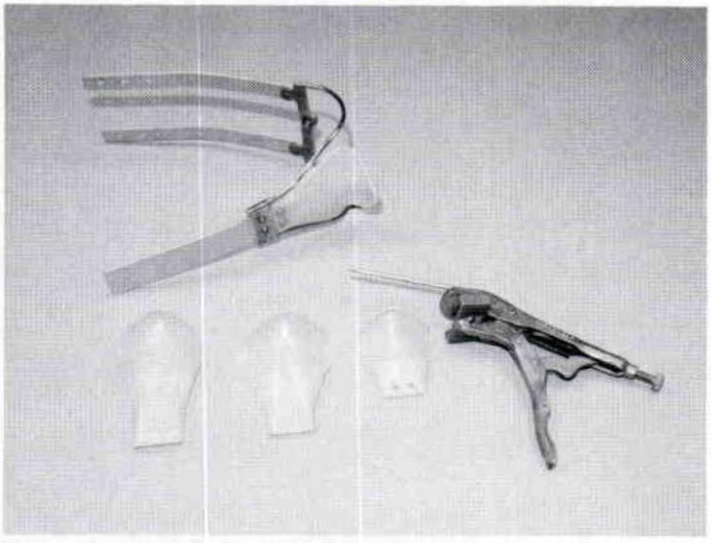

Figure 8. Mandibular support and forming tool.

in the neck ring upon closure (Figure 5-A, 5-B). This second design is probably the most cosmetic and functional to date.

In its initial clinical evaluations, Durr-Fillauer has experienced the same measure of positive response that we did. Moreover, the impression exists that more C.T.L.S.O.'s are being prescribed than before. The supposition is that with the superior cosmesis afforded by the low profile neck ring versus the traditional neck ring, the physician is prescribing the C.T.L.S.O., instead of the T.L.S.O., for borderline patients.

In addition to the modified neck ring, Durr-Fillauer has also developed a mandib-

ular support of subortholen (Figure 6). Their intention with this support is that it can be used in an initial fitting to remind the patient to maintain correct posture. Subsequently, after the first month or so, when proper habits have been established, it may be removed. This would seem to be particularly useful in treating kyphosis. The subortholen mandibular support is molded in one size and trimmed to the proper length. A special tool is used to form the channel in the inferior portion of the support and doubles as a drill guide for the attachment holes (Figure 7).

SUMMARY

The orthotic staff at Children's Hospital at Stanford, with help from Carlton Fillauer, C.P.O. and Karl Fillauer, C.P.O. has developed, tested, and evaluated a new cervical neck ring for use on the C.T.L.S.O. The neck ring provides lateral cervical correction, low visibility, and correspondingly better cosmesis.

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I would like to express my thanks to Carlton Fillauer and his staff for their suggestions and help in creating this new neck ring, Gretchen Hecht, C.O., and Gary Bedard for their feedback and encouragement in the development of this project, and the entire staff at the Rehabilitation Engineering Center of Children's Hospital at Stanford for their help and support.

AUTHOR

Greg Moore, R.T. (O), at the time of the article, was a staff member at Stanford Children's Hospital.

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The Delivery of Orthotic and Prosthetic Services in America—A Physical Therapist's View

Donald G. Shurr, L.P.T., M.A.

INTRODUCTION

At a time when we hear much talk about competition, regulation, and reimbursement, and their impact on the health delivery system in the United States, it seems appropriate to take a step back and look at where orthotic practice has been and where it might be headed.

The overall purpose of this paper is to describe the development and practice of orthotics in the United States. I will provide some background on the historical development of the field, and examine the supply of, and need for, orthotic personnel in the United States. A number of educational programs provide training, and these will be discussed. Membership in professional organizations and certification will be described previous to the provision of data specific to device fabrication and delivery. My conclusion will provide perspectives on the future of orthotics and prosthetics in the United States.

HISTORICAL DEVELOPMENT

The word "orthotics" is taken from the word "orthostatic," from the Greek "ortho," to straighten, and "statikos," to cause to stand.[1] According to Dr. Sydney Licht in the "Preface to the First Edition" of *Orthotics, Etc.*, the word "orthotic" is relatively new. Connoting the field of straightening deformities with external supports, it was first used by Dr. Vern Nickel in a report of conferences on upper extremity devices for the National Foundation of Infantile Paralysis Respiratory Centers in 1953.[1] "Orthotics" was originally adopted in 1960 by orthotists and prosthetists in America when they formed the American Orthotic and Prosthetic Association from the original Artificial Limb Manufacturers' Association.[2]

Although it first meant the straightening of deformities with external support, the term orthotics today refers to the profession, including the art and science of the application of a device applied or attached to an external surface of a body to improve function. As was noted by Dr. Licht,[2] the field of orthotics now has expanded to include many systems, devices, and technologies which not only are unattached to the patient, but technically do not fall under the umbrella of the term orthosis—thus the use of the term "etcetera" in the title of his ninth volume by Williams and Wilkins.

Orthotics or Orthetics?

According to Dr. Sidney Licht,[2] one classics scholar believes that prosthesis means both the replacement of a lost part and help for a part. Orthosis means to straighten. Neither word adequately describes the field of orthotics and prosthetics as practiced today, or that which will be practiced in the future.

In 1955, Dr. Robert L. Bennett of Warm Springs, Georgia, used the word "orthetics" to describe an exhibition of braces

used to increase function in severely disabled persons.[2] Despite the fact that the word "orthetic" is relatively new, we are fortunate in that a rich history in the field reflects a rational and orderly development from seemingly simple beginnings.

The history of bracing or splinting, as it was called, can be separated into two parts. The first may be considered a non-surgical period between the time of Hippocrates through the 19th century. During this period, treatment consisted of manipulation and the application of orthotic appliances. The second era, the era of modern orthopaedics, relies on the use of antiseptic and aseptic surgery and more modern orthotic designs and materials.

Pioneers of the early period were Ambroise Pare (1509-1590); Dr. Hugh Owen Thomas (1834–1901), the "bonesetter" for whom many items are still named; and Sir Robert Jones, a nephew of Owen Thomas, who may be considered the "father of orthopaedic surgery." All were accomplished and innovative bracemakers.

Surgery gradually replaced bracing as the keystone in the practice of orthopaedics, and the bracemakers moved from physicians' offices into hospitals or private offices. Although some remain today in hospitals, the office practice of the independent practitioner businessman continues as the model.

During the last half-century, two events served to focus attention on the role of orthotics and prosthetics. Soldiers injured in World War II benefited from the services of those trained to develop and provide for the artificial replacement of limbs. Following the increased interest in prosthetics due to World War II, a similar interest in orthotics arose via the National Foundation for Infantile Paralysis, following the two polio epidemics around 1950.

According to Dr. Vern Nickel,[1] the development of respirators and tracheostomies created a need for better upper extremity orthotics and people to design, fabricate, and fit them. The need for manpower in the orthotics industry led to the development of formal educational programs, producing orthotists and prosthetists, starting in 1956. These programs have grown both in numbers and in scope since the first baccalaureate degree in orthotics began in 1962.

SUPPLY OF TRAINED PERSONNEL

In order to meet the patient orthotic and prosthetic needs of the future, one must consider both the projections for practitioners and for manpower in related professions, since orthotists and prosthetists deal in a medical and paramedical arena.

In 1982 there were 66,485 medical students in training in the United States, meaning 16,700 graduates each year.[3] They are trained by 53,750 full-time medical faculty, at a cost in excess of 6.3 billion dollars. There are 2,667 orthopaedic residents in 180 programs in America, and 605 Physical Medicine and Rehabilitation residents in 65 programs, down 50 from 1982. It is interesting to note that in the 1982 American Academy of Orthopaedic Surgery Manpower Survey,[4] 42 percent of those who responded felt there were too many orthopaedic surgeons in their geographic area. Plans call for these programs to continue to train 2,267 physicians each year in the years to come.

Now consider that there are currently 350,000 MDs and 15,000 DOs practicing in the U.S. By the year 1990, the combined number is projected to reach 560,000. Since many O&P professionals relate directly to orthopaedic surgeons, it is of interest to note that there were 12,250 fellows in the American Academy of Orthopaedic Surgery in 1982, and many more MDs without board certification doing orthopaedics. By 1990, it is projected that there will be 17,500 board certified orthopaedic surgeons. Additionally, there were 2,200 physiatrists, although their numbers are not growing nearly as fast as those of orthopaedic surgeons.

Of the non-physicians, nurses as a group comprise the largest number of providers of service, with about 1,360,000 in active service in 1982. Seventy-five thousand nurses are trained each year, up from 44,000 per year as recently as 1970. Contrary to what might have been written, according to the Institute of Medicine study

of 1983,[5] there was and is no shortage of nurses, only a problem of poor distribution and a difficulty in finding nurses to work in areas such as surgical intensive care. By 1990, there are expected to be two million nurses in America.

Physical therapist schools graduated 2,888 students in 1981 from 82 schools. Since new programs are continually being opened and accredited, that number should surpass 3,000 per year by 1985.

There are some 40,000 physical therapists in the U.S. According to recent Bureau of Labor statistics, a 1.9 percent unemployment rate exists for physical therapists, which is second only to physicians at 1.5 percent. In summary, it appears that there will be an increasing supply of orthopaedists and related professionals, and the impact of substitution among providers cannot be estimated at this time.

NUMBER OF ORTHOTISTS AND PROSTHETISTS IN PRACTICE SETTINGS

Since 1949 there have been more than 880 prosthetist/orthotists, 1,392 orthotists and 1,232 prosthetists certified by the American Board for Certification in Prosthetics and Orthotics, Inc. (ABC). On July 1, 1982, there were 817 COs, 739 CPs, and 580 CPOs in good standing. This total of 2,136 represented the current certified work force in orthotics and prosthetics (Figure 1). Assuming the present 2,136, an addition of nine to ten percent per year for eight years, and one to two percent retirement rate, by 1990 there will be approximately 4,000 orthotic/prosthetic practitioners in America, in contrast to 560,000 MDs, two million nurses, and 40,000 physical therapists (Figure 2).

At this point in time in the United States, orthotists and prosthetists practice in five major settings (Figure 3):

1. *Private offices.* Since the late 1880s, orthotists sought to move out of physicians' offices and hospitals in an effort to be independent providers of services and devices, and to avail such services to many physicians and patients. This practice setting remains the most prevalent.
2. *Institutionally Based Service/Consultation.* Many large institutions such as hospitals—particularly children's hospitals, rehabilitation centers, or rehabilitation and research institutes—provide orthotic/prosthetic services from an internal staff. Rehabilitation facilities draw upon many disci-

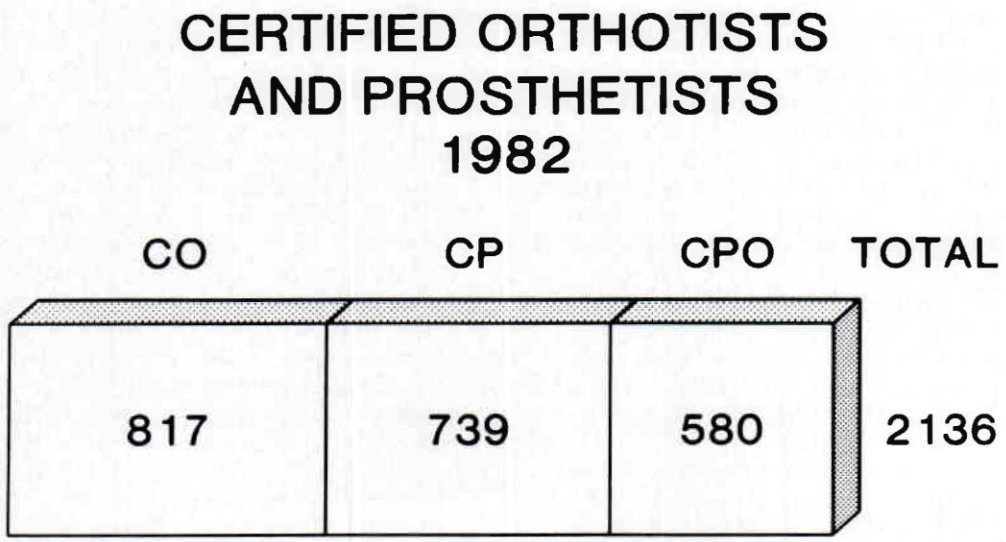

Figure 1. The total number of certified professional orthotists/prosthetists.

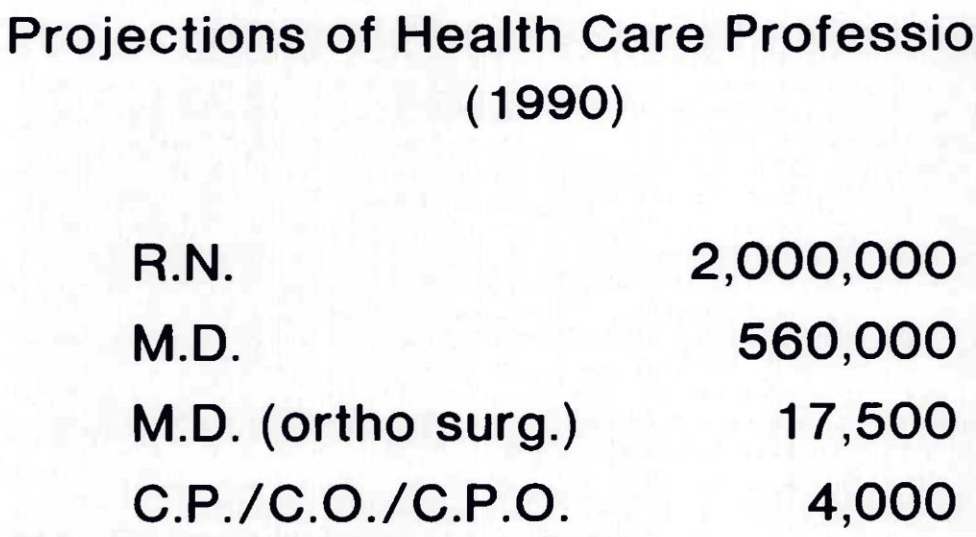

Figure 2. Projected number of health care professionals: 1990.

plines for their services. The range of services which may be found in a facility is reflected in the Vocational Rehabilitation Amendments of 1968, which describe a rehabilitation facility as providing "singly or in combination" one or more of the following services for handicapped individuals: (1) comprehensive rehabilitation services which include, under one management, medical, psychological, social and vocational services; and (2) testing, fitting, or training in the use of prosthetic and orthotic devices.

The fact that the statutory language speaks specifically of orthotics attests to the integral part in the rehabilitation process played by orthotists and prosthetists.

3. *Supplier and Fabrication Management.* The use of a central production laboratory external to the site of fitting or measuring will probably increase in the 1980s in America. In order for a successful transition into that mode, communication via the written and spoken word is essential. Without communication, central producation can be a nightmare.

   Since many O&P professionals may use the same production facility, highly skilled practitioners who can relate to others and their fitting or measuring problems are necessary. A phone conversation with an orthotist/prosthetist in the field from a knowledgeable and communicative fellow can make the difference between success and failure of a fitting, particularly of a new device, material, or application.

4. *Education.* In the 11 programs available for orthotic or prosthetic entry-level preparation, there are full-time professional faculty responsible for this education. According to the 1976 Ponte Vedra Report,[6] there were 17 full-time certified prosthetists, 24 full-time certified orthotists, and 13 full-time certified prosthetists/orthotists in this area of practice.

   The role of the educators in these facilities cannot be underestimated as they provide the source of the life blood for the future in orthotics and prosthetics. No similar data can be located on the current faculty numbers or locations.

5. *Research.* To the knowledge of this author, few, if any, people work in America today doing only basic research in orthotics/prosthetics. This is in no way to ignore those practitioners who are working on the cutting edge of materials, design, or rehabilitation engineering. However, no known orthotist or prosthetist performs only such

Figure 3. Orthotic/prosthetic practice settings.

research functions. It is included as a practice setting to emphasize the necessary role of research and development in the professions, even though few positions currently exist.

According to Dr. Colin McLaurin,[6] his final examination as a prosthetist, after seven years of training and apprenticeship as a journeyman, was to fit and fabricate a prosthesis from raw materials, to include the socket, knee, and foot. Although this approach apparently develops a skilled artisan, it does little to recognize the cognitive areas so necessary in the skills of the modern orthotist/prosthetist. With the skills currently being taught in the baccaleaureate programs, the professional is moving toward the status of independent prescription, fitting and fabrication, always maintaining the concept of the team which has worked so successfully in the past.

NEED FOR ORTHOTIC AND PROSTHETIC SERVICES

In the preparation of this paper, contacts with numerous offices, bureaus, and data sources were made in an attempt to identify the population in America in need of prosthetic and orthotic services. Although the question has never been addressed directly, the information presented was gathered from the National Health Interview Survey,[7] a nationwide household survey conducted by trained representatives from the U.S. Bureau of the Census. Using scientific sampling techniques, percentages of the population in need of specific devices were identified. These studies have been published in 1969 and 1977.

The results of these studies indicate that 6,250,000 people in America used orthoses, wheelchairs, canes, or special shoes in 1969. By 1977[8] the number had grown on 6,500,000, or about three percent of the

American population. Specifically, people using leg orthoses increased from 233,000 in 1969 to 400,000 in 1977. This represents roughly 1.2 people per thousand population in 1969 to 1.9 people per thousand in 1977.

Looking at the potential market from another perspective, there were 1,392,000 Americans in 1971 having partial or complete paralysis, or 6.9 per thousand population. Of those, 200,000 were victims of hemiplegia. By 1977, the numbers had grown to 1,532,000 people, 237,000 of which were hemiplegic, or about 7.2 per thousand. Spinal cord injuries totaled 150,000, with eight to ten thousand new cases occurring each year.

Of interest is the fact that for the same population survey, those using prosthetic legs numbered .6 per thousand in 1969, or half of those using orthoses. By 1977[8] the figures had jumped to one per thousand using an artificial leg and 1.9 per thousand using leg orthoses or, again, nearly half. Total people reporting using either artificial legs or arms in 1977 were 275,000.

EDUCATIONAL PROGRAMS

There are currently 12 practitioner-level programs located in the United States.[9] In addition, there are four technician or assistant-level programs. There is also a practitioner residency training program of one year in length at the Newington Children's Hospital, Newington, Connecticut, whose stated purpose is to allow a graduate orthotist one year of specialized education under supervision, dealing specifically with the orthotic needs of children. Since the residency concept is not new to medical and paramedical education, it is unfortunate that it took until 1980 to get the first program under way.

Using the stated enrollment figures published in *Orthotics and Prosthetics*, Fall, 1982,[9] 175 students will graduate per year from these 12 schools. It should be noted that 30 of the 175 students, about 17 percent, come from the Army orthotic school, whose model differs from most others in that no formal education is required prior to admission. According to the current standards of ABC, graduates of this program do not qualify to sit for the orthotic board examination and therefore do nothing to increase the credentialed manpower in the field for the future.

In keeping with a resolution passed at the Ponte Verdra meeting of 1976, there is only one sub-professional in orthotics and prosthetics, the technician. It was also recommended that only the education program be certified by ABC, and the technician be registered, as opposed to being certified.

PROFESSIONAL ORGANIZATION/ CERTIFICATION

Certification of both professionals and facilities is administered by the American Board for Certification in Orthotics and Prosthetics, Inc. This board was established in 1948 through a combined effort of the orthotic and prosthetic industry and the American Academy of Orthopaedic Surgeons.[10] The ABC promotes high professional standards, high quality facilities, and develops and administers examinations in prosthetics and orthotics. Additionally, the organization serves as an appeal committee for alleged violations of established standards of practice, ethics, or law.

DEVICE FABRICATION AND DELIVERY

There is no data which describes the state of affairs in America today with respect to the subject of fabrication or prefabrication. Costs associated with certified personnel, plastics, ovens, vacuum forming, and Occupational Safety and Health Administration regulations in the late 1960s and early 70s gave birth to the concept of central fabrication, or production of devices from a centralized geographical location, often apart from the fitting center or office. Central fabrication allows technol-

ogy to be applied rapidly, without the need for each facility to purchase, use, and maintain expensive, modern, high-technology equipment.

Central fabrication is a natural extension of prefabrication, concentrating on any device which can be mass produced in predetermined sizes, lengths, thicknesses, or configurations. This feature allows the practitioner to modify the device to fit any change necessary. If the entire device needs custom fabrication, it too can be fabricated at a centralized location from a cast or mold taken by the certified practitioner and sent to the laboratory. This system is analogous to the current production of dentures, eyeglasses, and other medical or dental devices.

When central fabrication was first developed, it was done to allow the practitioner more time to do other things. In the future, it will allow the practitioner to survive, as profit margins will be held in check by governmental controls put in place in an effort to control health care related costs.

In a recent survey compiled by Charles H. Pritham, CPO,[11] 17 percent of the respondents indicated that their patients in need of leg orthoses received 100 percent plastic devices. Sixty-one percent indicated that they delivered 75 percent plastic and only 25 percent metal, whereas only 15 percent used less than 25 percent plastic and, therefore, 75 percent metal orthoses. Reasons cited for using plastic instead of metal were weight, cosmesis, versatility, etc. Of those responding, the most commonly cited disadvantage of the plastic ankle-foot orthosis (AFO) was the inability to adjust the ankle in dorsi- or plantar-flexion. No data exists concerning criteria used for such plastic or metal AFO fittings. Therefore, the data in this survey is incomplete. Since the process from prescription through fitting may involve a number of professionals besides the orthotist, consistency between geographical areas or facilities may be difficult to demonstrate—even in the presence of increasing central fabrication availability.

An analysis of certified orthotic and prosthetic facilities in America reveals a total number of 521.[10] Of these, 119 are certified in orthotics, 123 are certified in prosthetics, and 279 are certified in both. These facilities are most numerous in the states of California (54), Michigan (35), New York (34), Ohio (34), Illinois (33), and Pennsylvania (28).

Since there are about 220 million people in America, there are about 10 certified facilities per state on an average, or one facility for 422,000 population. Obviously the state averages are difficult to use. Some states, like Wyoming, have no certified facilities and therefore have distribution problems—even though, as in Wyoming's case, the state may have a relatively small population.

The Veterans' Administration (V.A.) is the largest orthotic and prosthetic central purchasing and delivery system in the United States. According to information supplied by Mr. Frederick Downs, Jr., Director of Prosthetic and Sensory Aid Services for the V.A.,[12] in the fiscal year 1981–82, the V.A. spent nearly 100 million dollars. This includes all phases of prosthetic-orthotic activity, from training programs to testing and distribution of devices, to direct prosthetic device services. Total cost associated with the provision of 130,313 orthotic appliances was $6,096,997, of which nearly 80 percent was internally supplied. Total prosthetic devices and sensory aid supplies numbered 1,330,767, at a cost of $79,115,303. Included in the internally supplied category are custom fabricated shoes, a service not readily commercially available.

THE FUTURE FOR ORTHOTICS AND PROSTHETICS

The future for orthotics and prosthetics in America appears headed in the direction of other allied health care, but different from the other medical and paramedical models (Figure 4). The data clearly demonstrate that by the year 1990 there surely will be present an oversupply of fully trained physicians, about 560,000 in number, or 70,000 in excess of predicted needs. The supplies of nurses and other allied health

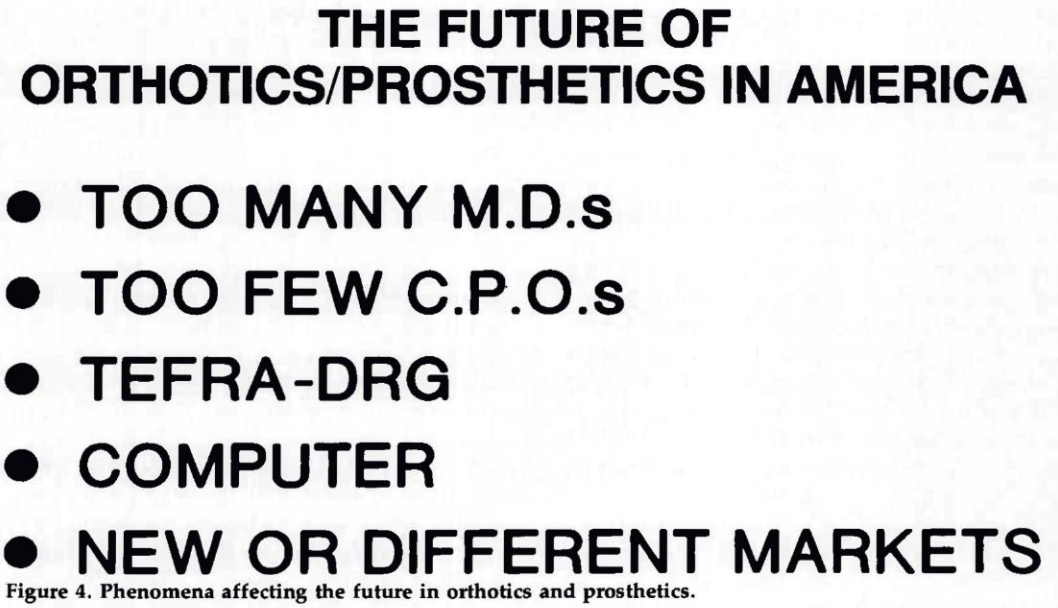

Figure 4. Phenomena affecting the future in orthotics and prosthetics.

professionals, while larger, are not predicted to be in excess by 1990. There will surely be a shortage of certified orthotists/prosthetists by 1980 standards. However, the federal policies which will be necessary to deal with the physician excess will certainly have an effect on other providers such as orthotists and prosthetists.

Two theories which describe what may occur as a result of this physician oversupply suggest some interesting propositions.[13] One theory, the pyramid model, predicts that the group at the top, the physicians, will react to the oversupply by reclaiming many tasks which had previously been delegated to nurses, therapists, orthotists, or others, in times of shortages of physicians or growth. The second theory predicts that the forces of a competitive marketplace will cause physicians to increase their productivity by using more assistive personnel, resulting in an overall growth for all.

Another factor which may affect the future of orthotics is the impact of what has come to be known as TEFRA, or the Tax Equity and Fiscal Responsibility Act of 1982. These 1982 amendments to the Medicare Section of the Social Security Act propose the most far-reaching changes in health care reimbursement since the beginning of the program in 1965.

In 1982, the United States spent 322 billion dollars for health care, of which 42 percent was for hospital care and 19 percent was for physician services. Although the figures of $136 billion for hospital care and $62 billion for physicians are staggering, more staggering is the rate at which these dollar values rose over 1981: about 14.9 percent. These figures are providing many with the evidence they feel they need to limit or to put "caps" on reimbursement. It remains to be seen how these reimbursement pressures may alter the practice of orthotics, but it is clear that there will be incentives to hold down fees.

Hospital care was the largest part of the 10.5 percent of the Gross National Product spent for health care in the United States last year. The changes which TEFRA includes were primarily aimed at non-physician costs associated with the Medicare program. These changes will replace a charge system of routine per diem cost limits with a system of limits on total operating cost-per-case, based on each diagnostic related grouping, or DRG. Each patient admitted to the hospital will be assigned a DRG for payment purposes. Payment will then be made on an average length of stay assigned for that particular

DRG. Any days of inpatient care in excess of the approved standard will not be reimbursed to the hospital. The DRG system is the mechanism chosen to implement a prospective payment system, with the overall goal of the program being to control future increases in cost to the federal government on behalf of the Medicare program.

The new payment concept represents the first fundamental change in the payment system for America's hospitals in 50 years. All combinations of the 11,828 diagnoses and 33,000 procedures currently included within the coding system of the *Internal Classification of Diseases* have been consolidated into 468 diagnostic related groups. Payment will be calculated on the basis of the average cost of care for patients in each DRG through the nation's 6,000 acute general hospitals.

What is not clear at this point is what effect this and future program changes will have on O&P services delivered to Medicare beneficiaries, but more importantly, what effect this program change will have on other purchasers of these services, namely private commercial insurers, and Blue Cross. In Iowa, for example, the Insurance Commissioner has called for a prospective payment model to be put in place along with the changes in Medicare. Since in many states Blue Cross acts as the fiscal intermediary for Medicare, there are likely to be many similarities between Medicare and Blue Cross.

The concern for all of us with these trends and changes are the potential for erosion of non-physician or non-hospital services to be capped, cut, or severely limited at the expense of more expensive, better lobbied, inpatient hospital or physician delivered care.

The future for orthotics and prosthetics promises a better engineered, more effective, less-expensive-to-produce product, and the accompanying service of the professional, well trained and experienced in appropriate orthotic applications. Orthotic applications for poorly understood problems will challenge the orthotist of the future. Challenges such as prophylactic knee orthoses represent a revolution in the prevention of injuries in contact sports, such as football. Other applications in the work setting would assist workers with certain stressful tasks, attempting to prevent or reduce the severity and numbers of injuries which result in lost time from work and an overall loss of productivity. This future will certainly involve the use of computer assisted design, modification, and perhaps even fabrication. Mr. Jim Foort in British Columbia has developed a computer assisted program for below-knee socket design, modification, and fabrication. In order to integrate the computer into the practice of orthotics and prosthetics, engineers will be called on for their assistance, continuing to consummate this marriage between orthotists and engineers.

It appears clear that, if the predictions hold true, there will be a shortage of orthotists/prosthetists in 1990. Physicians will undoubtedly be treating many patient types who, like their counterparts of yesterday, will be survivors, due to advances in medical knowledge or technology, allowing even normal people to live longer lives. Along with that challenge goes an equal challenge to make that longer life more functional than previously experienced. Therein lies the challenges for the orthotists and prosthetists of the future.

NOTES

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[7]*National Health Survey*, "Use of Special Aids—1969," DHEW Publication Number HSM 73-1504, Rockville, 1969.
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An Alternative Approach to Fitting Partial Hand Amputees

Russell D. Brown, C.P.O.

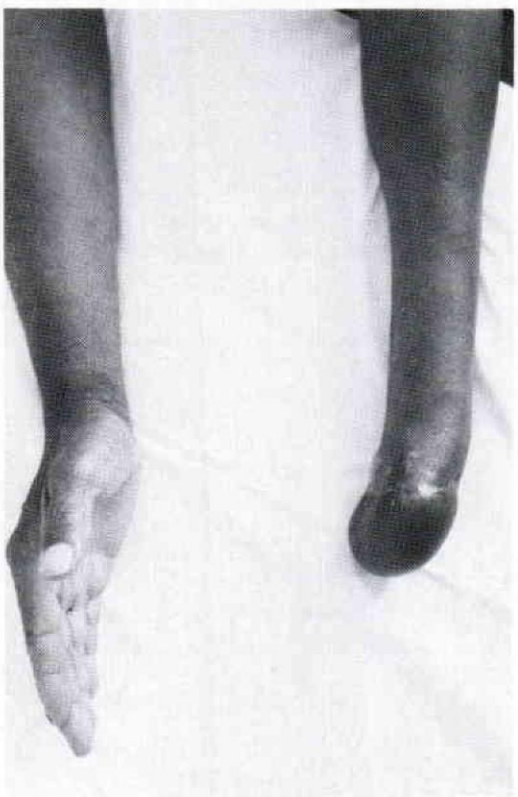

Figure 1. The prosthetist is often faced with having to treat cosmetically the length of the residual limb in the partial hand amputee.

Some surgeons believe in saving as much of the residual limb as possible when performing an amputation. Because of this, the prosthetist is sometimes faced with the challenge of producing a prosthesis for the upper limb amputee who may, in the opinion of many prosthetists, have too much of the original limb left to treat cosmetically (Figure 1). We are accustomed to having room for a wrist unit at the end of the socket to contain the terminal device. For those of you who have run into this situation, I would like to share what I have found to be a successful solution.

These amputees are usually strong, and eager to use the affected limb to its full advantage. They are also usually unwilling to have surgical revisions made. In most cases, by the time of prosthetic intervention, the residual hand is already being used to assist the sound side. In addition, little atrophy may be apparent due to the partial usage.

Selection of a terminal device may be a problem because of the length of the device added to the traditional prosthesis. The Prehensile Hand® which is available through Therapeutic Recreation Systems, Inc.,[1] has the ability to set the functioning surfaces of the device in the proper relationship with the extremity (Figure 2).

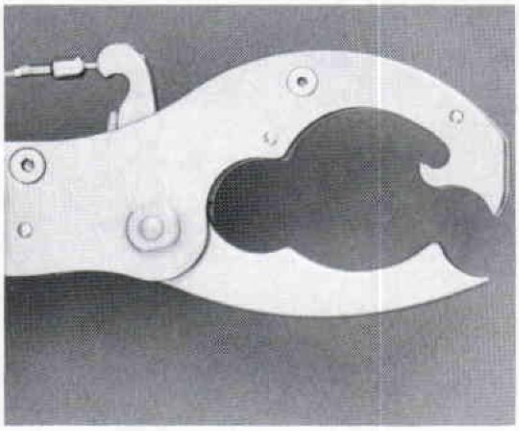

Figure 2. The prehensile hand, supplied by Therapeutic Recreation Systems.

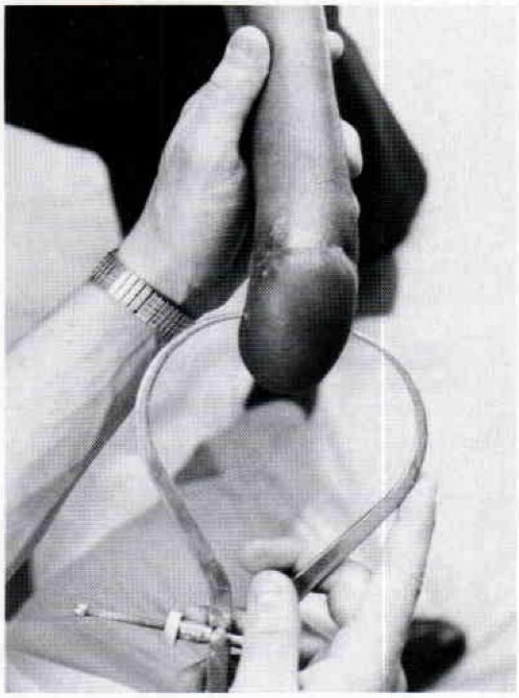

Figure 3. As a result of the bulbous shaped distal end, suspension may be achieved easily.

Furthermore, this voluntary closing terminal device blends well into the natural reflex habits of the amputee, so the ease of its use is also a plus with this type of prosthesis.

The advantages of the partial hand amputation become apparent as one forms the socket. As a result of the bulbous distal end, suspension may be achieved easily by the use of an expandable dorsal window (Figure 3).

The same provisions for the loading and unloading of forces are taken in making the negative mold as with any other upper limb casting procedure (Figure 4).

Supination and pronation are not usually blocked at this level. Full advantage can be taken of this control by getting a narrow medio-lateral dimension with the negative mold (Figure 5).

Figure 4. Provisions for the proper loading of forces begin, as always, with a good cast.

Figure 5. Supination and pronation control may be maintained by obtaining a narrow medio-lateral dimension in the negative mold.

Fastening the terminal device to the prosthesis is accomplished by removing the threaded male base plate, which is attached to the Prehensile Hand with two hard screws, and applying a new foundation, which is created by duplicating the same dimensions of the distal end of the base plate with a piece of S.T. 2024, ¼" × 2" aluminum bar and riveting a stabilization bar (Figure 6). Another plate of stainless steel is shaped to fit the flat surface of the aluminum base and yet be contoured to the volar distal end of the socket. This base plate is to be laminated into the socket.

The new socket base plate is tapped to receive screws placed through clearance holes in the aluminum base. Other multiple holes are drilled in the stainless steel base plate to increase the mechanical bond created at the time the plate is laminated into the prosthesis.

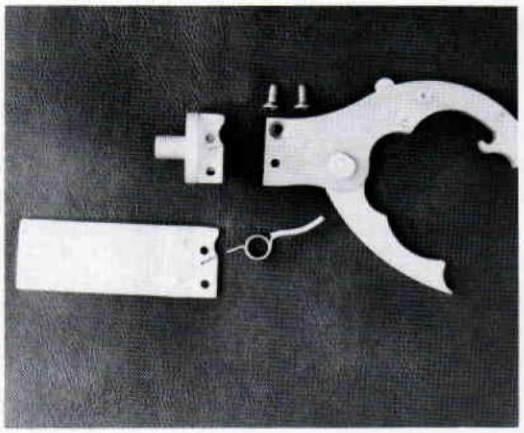

Figure 6. The component parts of the terminal device showing the new adapted flat base plate which replaces the threaded standard base plate.

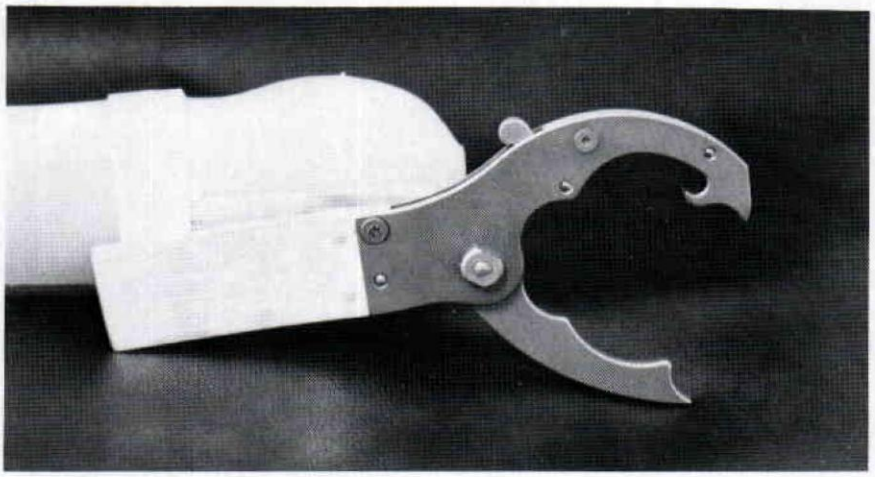

Figure 7. At the time of the trial fitting, adjustments may be made to place the terminal device in the position of best function.

At the time of the trial fitting, examine the socket as usual, and make any necessary adjustments. The stainless steel plate can now be positioned to hold the prehensile hand in the most functional position (Figure 7).

To complete the prosthesis, laminate the stainless steel plate in place and align the terminal device. Don the prosthesis using the dorsal window and the Velcro® straps. The cable may now be aligned (Figure 8).

We have found that a #9 harness affords the best function of the device (Figure 9). The adaptability of the amputee with ease of function has been gratifying. He not only can perform intricate movement, but is also capable of heavy manual labor as well (Figure 10).

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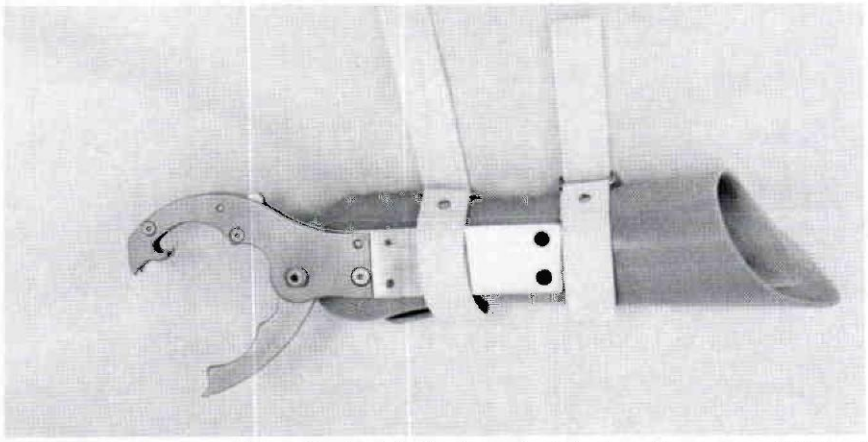

Figure 8. The completed prosthesis with final terminal device alignment and Velcro® closures.

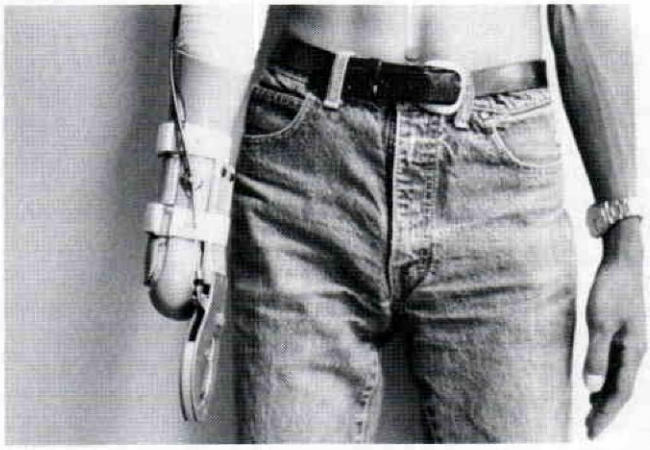

Figure 9. The appearance of the finished prosthesis on the patient demonstrating approximation of length.

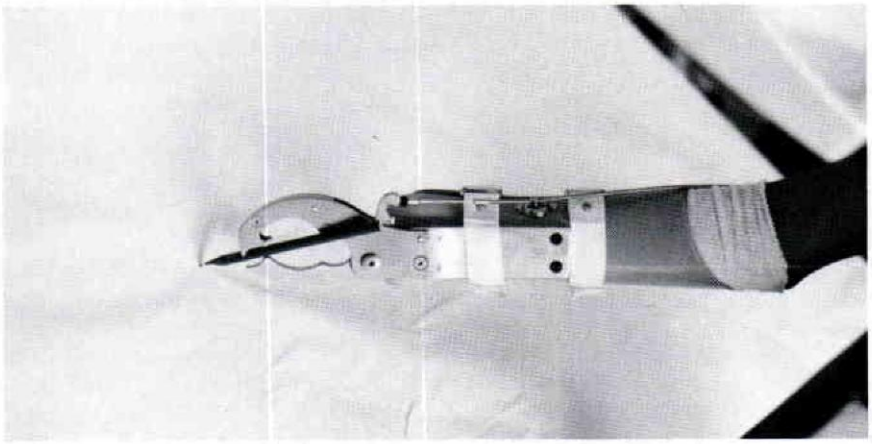

Figure 10. The patient, while able to participate in heavy manual labor, is also capable of intricate movement.

Orthotics and Prosthetics, Volume 38, Number 1, Spring, 1984, pp. 68-70.

Technical Note— Case Study: A Multiple-Form Plastic Ankle Foot Orthosis

David C. Showers, C.P.O.

INTRODUCTION

There are universally accepted orthotic designs for the patient who presents weak ankle dorsiflexors coupled with swing and stance phase lateral instability of the subtalar joint. In most cases, these standard designs are adequate for the problem. However, the orthotist will occasionally have a patient on whom the routinely prescribed Ankle Foot Orthosis (A.F.O.) designs are unsatisfactory or unacceptable. In one such case, illustrated within, a Multiple-Form molded A.F.O. was devised to meet the extraordinary needs of the patient. In select cases, the orthotist may find this Multiple-Form molded A.F.O. a valuable alternative design.

CASE HISTORY

A twenty-eight year old male was diagnosed as having permanent nerve damage in his left leg as a result of a fall down a flight of stairs. On examination, he exhibited weak ankle dorsiflexion and lateral instability of the subtalar joint. The patient himself complained of pain and instability of his ankle when standing or ambulating Moreover, the muscle imbalance in his leg was a potential cause of contractures.

Two different types of Ankle-Foot Orthoses had been prescribed, used, and subsequently rejected by the patient. The first was a solid-ankle, custom molded, polypropylene A.F.O. which unnecessarily restricted ankle plantarflexion and dorsiflexion. The second orthosis was a double-upright A.F.O. with dorsiflexion assist and a lateral control T-strap attached to the shoe. The patient found this orthosis bulky, noisy, cosmetically unacceptable, and not truly supportive, as the foot continued to invert inside of the shoe.

TREATMENT

When this patient was referred to me, I recommended a custom molded plastic ankle foot orthosis with articulated ankle and dorsiflexion assist.[1] Although this design would have been functional and supportive, the patient rejected the idea of having metal ankle joints.

Since any use of metal joints would be refused, I designed a custom molded single-form A.F.O. with medial and lateral extensions to control the M-L instability.[2] The patient accepted the design, but the difficult to finish ankle trimline sacrified purchase area, reducing the effectiveness of M-L support. Also, the design was prone to fatigue and breakage in the narrow curves.

The final solution was found in designing a Multiple-Form Plastic A.F.O. combining a posterior leaf-spring Molded A.F.O. and an overlapping reinforced form extending medially and laterally for rigid support. The patient was satisfied with the

function, support, and cosmesis of this orthosis. His physician and therapist approved after their respective evaluations.

FOLLOW-UP EVALUATION

Five years later, the patient was seen for an updated evaluation. The medical team concluded that the orthosis was still functioning well and it was refurbished with new Velcro® closures and new plastizote® malleoli padding (Figures 1, 2). The team was pleased to find that the patient's ankle joint was not rigid and that he had not developed a varus contracture at the subtalar joint. The patient now receives six month periodic evaluations due to the age of his orthosis.

FABRICATION AND FITTING

A standard design, polypropylene, posterior leaf spring, molded A.F.O. is fabricated and trial fitted to finalize a trim line that will support the weak dorsiflexors, yet allow flexibility for normal active plantarflexion. The completed leafspring section is again placed on the plaster model and a second polypropylene form is vacuum formed over the first. The second form should be reinforced with strips of polypropylene.[3] From this, a section to control medio-lateral instability will be cut and fitted for optimum function (Figure 3). The distal posterior underside of the second form must be beveled generously to prevent the stress of repeated plantarflexion from causing premature fatigue of the plastic. The second form is secured with screws to the mid-calf section of the first form allowing for easy removal for trimline adjustments (Figure 4). Velcro® closures keep the leg positioned in the orthosis.

CONCLUSION

The Multiple-Form Plastic A.F.O. is made of two sections, a posterior leafspring A.F.O. for antero-posterior control, and a reinforced second form for medio-lateral control. This orthotic design was

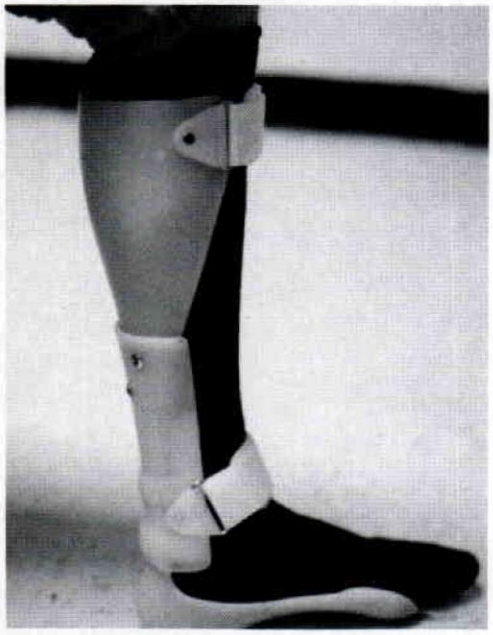

Figure 1. Medial view of multiple form plastic AFO.

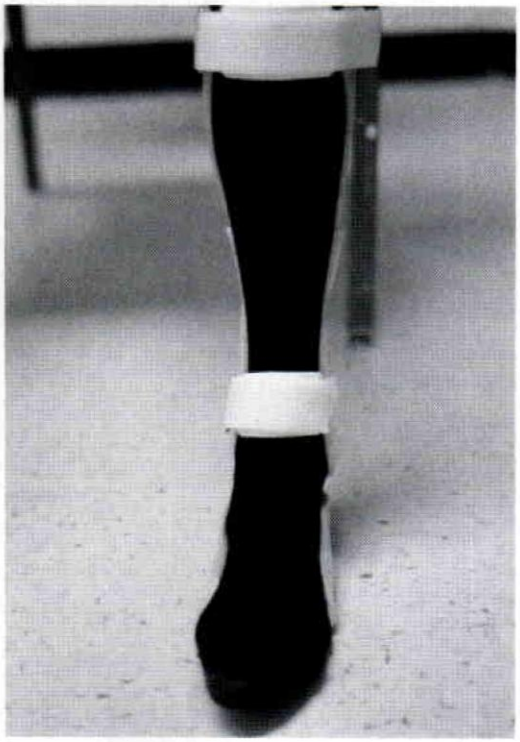

Figure 2. Anterior view of multiple form plastic AFO showing minimal anatomical change.

Figure 3. Lateral view of the multiple form plastic AFO showing the added material at the ankle to provide sufficient control of the lateral instability. The trim line is crucial in this area.

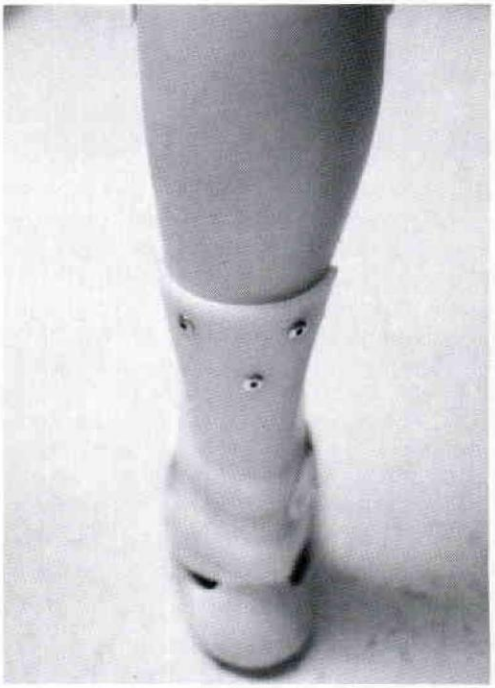

Figure 4. Posterior view showing the attachment points of the second form.

able to meet one patient's needs for maintaining ankle function, preventing further subtalar instability or deformity and displaying acceptable levels of visual, auditory, and sensory cosmesis. Whereas most patients who display weak dorsiflexors and lateral instability can be accommodated through more standard orthotic designs, it is suggested that the Multiple-Form molded A.F.O. may be useful in select situations.

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[1]Bensman, Alan S., "A New Ankle-Foot Orthosis Combining the Advantages of Metal and Plastics," *Orthotics and Prosthetics*, Vol. 33, No. 1, March, 1979.

[2]Sabolich, John, "Modification of the Posterior Leaf Spring Orthosis," *Orthotics and Prosthetics*, Vol. 30, No. 3, September, 1976.

[3]Showers, David C., and David Laird, "A Reinforcing Technique in Orthotics and Prosthetics, *Orthotics and Prosthetics*, Vol. 36, No. 2, Summer, 1982.

ACKNOWLEDGMENT

The author would like to acknowledge Martha Strunck, C.P. for her assistance in preparing this article.

AUTHOR

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Orthotics and Prosthetics, Volume 38, Number 1, Spring, 1984, pp. 71–72.

Technical Note:

The Application of Nickelplast in Fabricating a PTB Insert

Glenn Kays, B.S., C.P.O.
Greg Scott, B.A., C.P.

For several years, we have been experimenting with various materials in an effort to develop a PTB insert that would meet the following criteria:

1. Ease of fabrication
2. Appealing cosmesis
3. Ease of modification
4. Material integrity that is not compromised under weight bearing

In our opinion, Kemblo and PELITE™, the materials of choice in the past, do not satisfactorily meet the above criteria. Nor do Aliplast, Lynadure, Spenco®, PPT, or silicone gel. Nickelplast[1] is the material that has come the closest to fitting our needs.

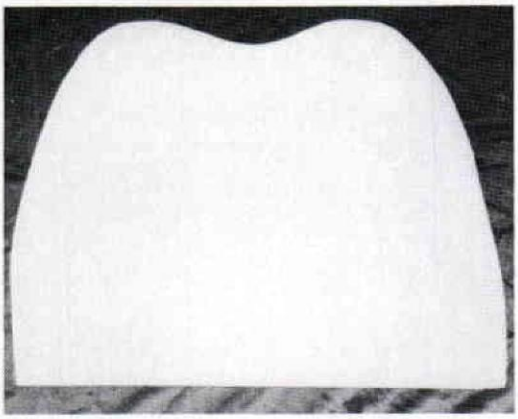


Figure 1. A pattern is made of the Nickelplast material according to the measurements of the positive model.

FABRICATION

The steps in fabricating the Nickelplast insert are as follows:

1. Lay up the leather interface in the normal fashion.
2. Cut a pattern out of 3/16" Nickelplast as shown in Figure 1.
3. Skive one side of the material, on a drum sander, at least one inch in from leading edge.
4. Glue the leather interface and Nickelplast with 3M contact cement or an equivalent adhesive.
5. Allow the glue to set five minutes, and then place the Nickelplast in the oven at 350°F for one minute, after which time the material will be flexible and easily worked.
6. Remove the material from the oven and place the skived edge of the Nickelplast along the posterior midline as shown in Figure 2. Continue to wrap the material around the positive model while moderately stretching and hand forming to insure a good bond between the materials.
7. Trim the posterior, leaving a one inch overlap, as shown in Figure 3. Glue the edge with poly adhesive,[2] and skive the overlapped material to provide a smooth seam.

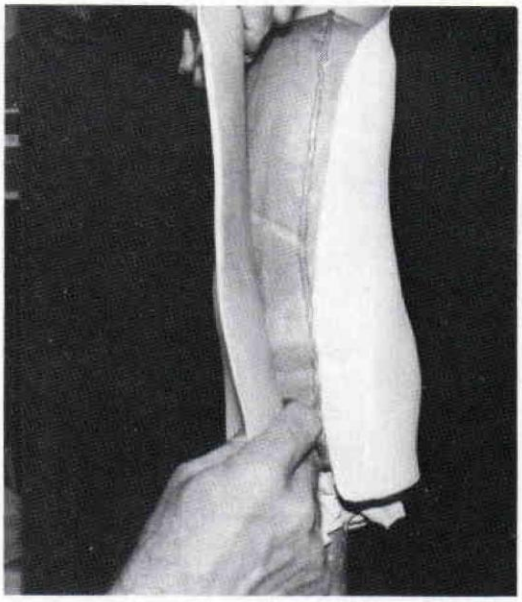


Figure 2. One edge of the skived material is attached to the midline.

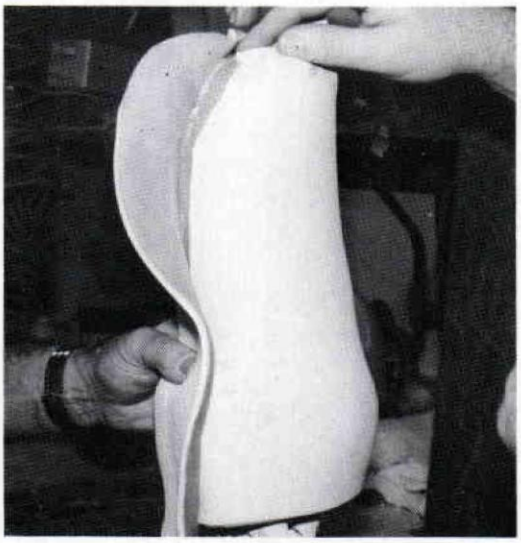


Figure 3. A one-inch overlap is made of the insert material after molding around the positive mold.

8. Cap the distal end with 3/16" Nickelplast using poly adhesive. Skive the distal end cap, pull a sheet of P.V.A. over the liner and laminate the socket in the usual manner. A finished insert is shown in Figure 4.

We have now been using Nickelplast, successfully, in the fabrication of PTB inserts for over two years. In this length of time we have fit ninety-two patients using this material. PTB inserts with supracondylar and suprapatellar suspension have also been successfully fabricated with nickelplast. On examination of the first inserts we fabricated from this material, we found that they held up better than inserts made from the other previously mentioned materials. Recently we have used Nickelplast in conjunction with silicone gel and other materials for management of difficult fitting problems. Patient acceptance is very good, and comfort and durability has increased over other inserts that they have worn.

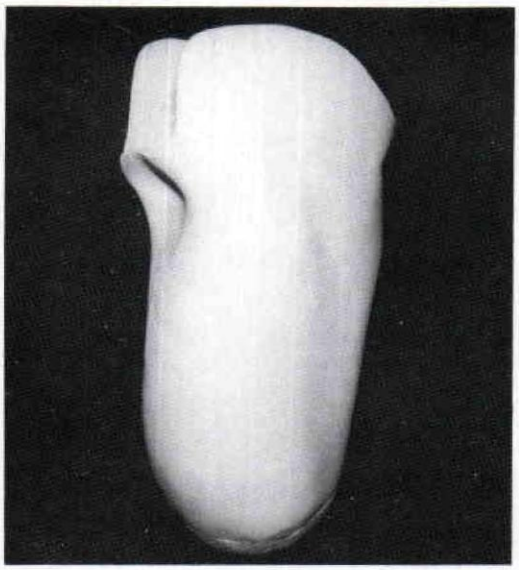


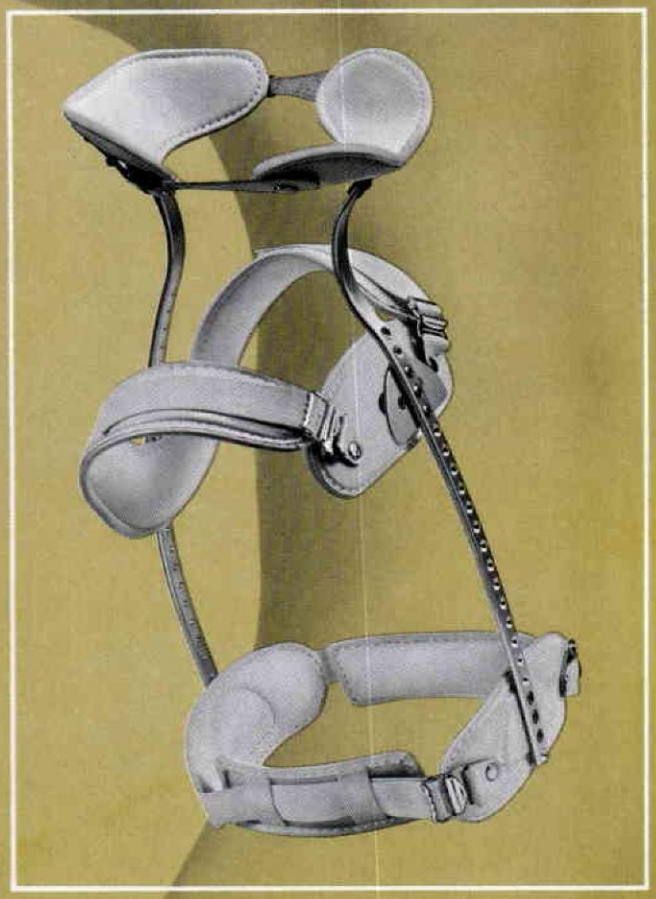
Figure 4. The finished appearance of the Nickelplast insert.

NOTES

[1]Alimed, Boston, Massachusetts.
[2]Cascade Orthopedic Supply Co., Chester, California.

AUTHORS

Mr. Kays and Mr. Scott are affiliated with Webb's K.E. Karlson Co., 533 S.W. Twelfth Avenue, Portland, Oregon 97205.



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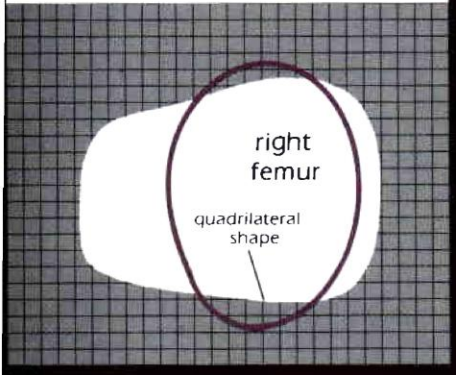

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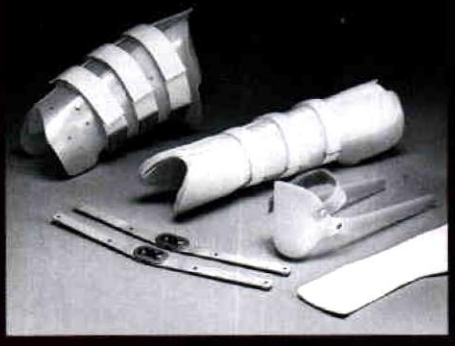

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REVIEWS

by Charles H. Pritham, C.P.O.

Tumor Prostheses for Bone and Joint Reconstruction: The Design and Application, Edited by Edmund Yee-su Chao, Ph.D. and John C. Ivins, M.D., Thieme-Stratton, Inc., 381 Park Avenue, South, New York, N.Y. 10016. 463 pages and index, 1983, $62.00.

This book reports the results of a workshop held in 1981. Fifty-eight papers are presented in the book, and apparently, even more were heard in the workshop, which included some 100 participants from around the world. Topics covered included surgery, chemotherapy, allograft reconstructive procedures, tumor endoprostheses, design considerations, implant materials, and attempts to assess the long term effects. While many of the papers were concerned with the pelvis and femur, the shoulder, humerus, and spine were also covered.

Any prosthetist who has been confronted with a patient who experienced amputation at a high level due to malignant cancer might well find this book of interest from a technical point of view. Unfortunately, it is apparently too early to properly assess the long term effects of surgically replacing a cancerous skeletal element with a man-made analog. While many papers of a technical nature are presented, there are very few that attempt to measure the patient's long term quality of life.

Sourcebook of Medical Communication, Robert C. Reeder, C.V. Mosby Co., 11830 Westline Industrial Dr., St. Louis, Missouri 63141. 308 pages, index, and bibliography.

Increasingly, health care professionals are being called upon to express themselves through a variety of media. Prosthetists/orthotists in particular have experienced a radical change in role in the past thirty years. Once, their time was spent primarily fabricating devices. Today they are quite likely to spend the majority of their time communicating with others both as individuals and in groups. In order to express ourselves effectively, it is necessary to understand how to use the media and resources available. Such is the purpose of this book.

Dr. Reeder, with the assistance of a large slate of contributors, has explored a diverse group of topics. Included are: how to write in a variety of formats, photography and slide presentations, office sketching, public speaking, and management of a scientific seminar. This latter section is particularly interesting as it includes suggestions for schedules and timetables, room arrangements, and dealing with the hotel staff.

This book is recommended as a practical primer. A number of provisions should be kept in mind, howeer. No book of this length can hope to treat such a large subject as this in depth, and in places the book is sketchy and in others is mildly repetitious. Dr. Reeder is a plastic surgeon and much of the material is specifically concerned with the particular needs of this branch of medicine. This latter point, however, is hardly a serious objection and does not detract from the general utility of the book.

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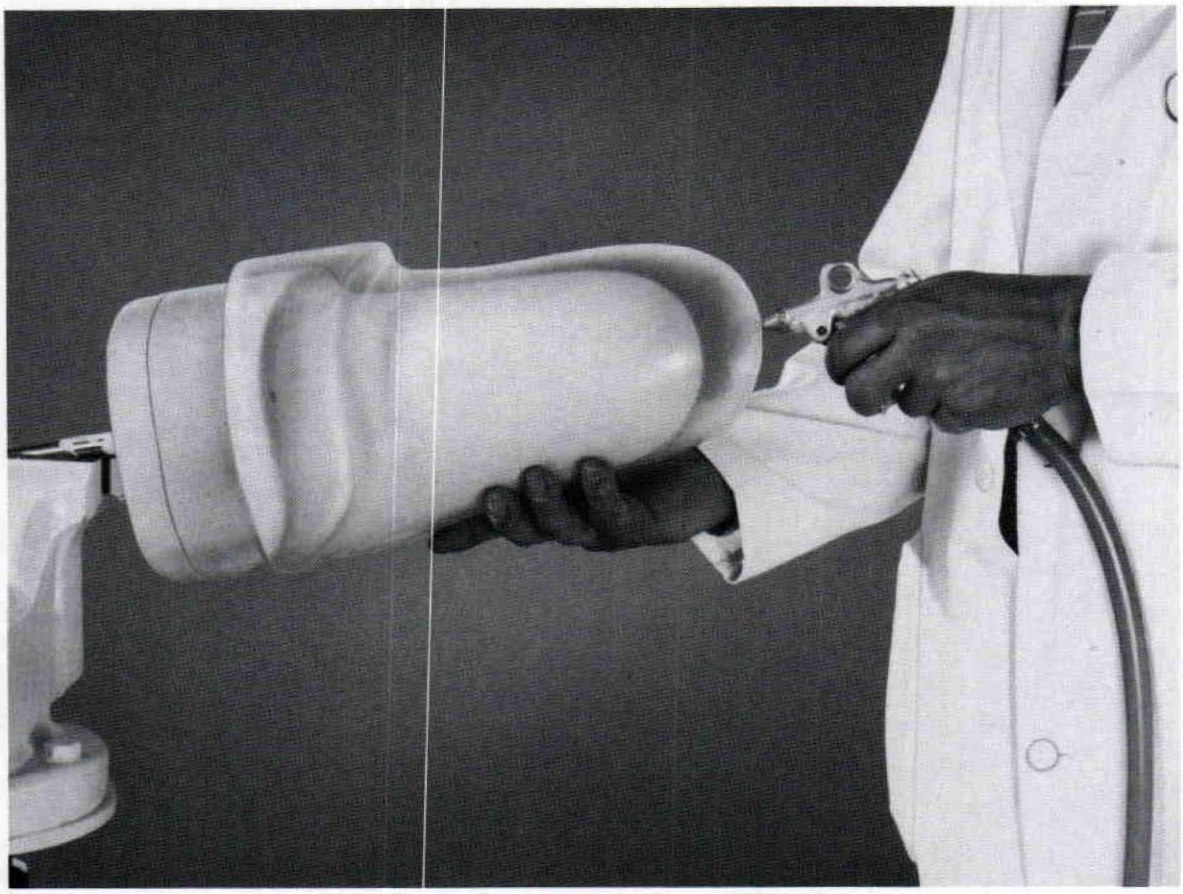

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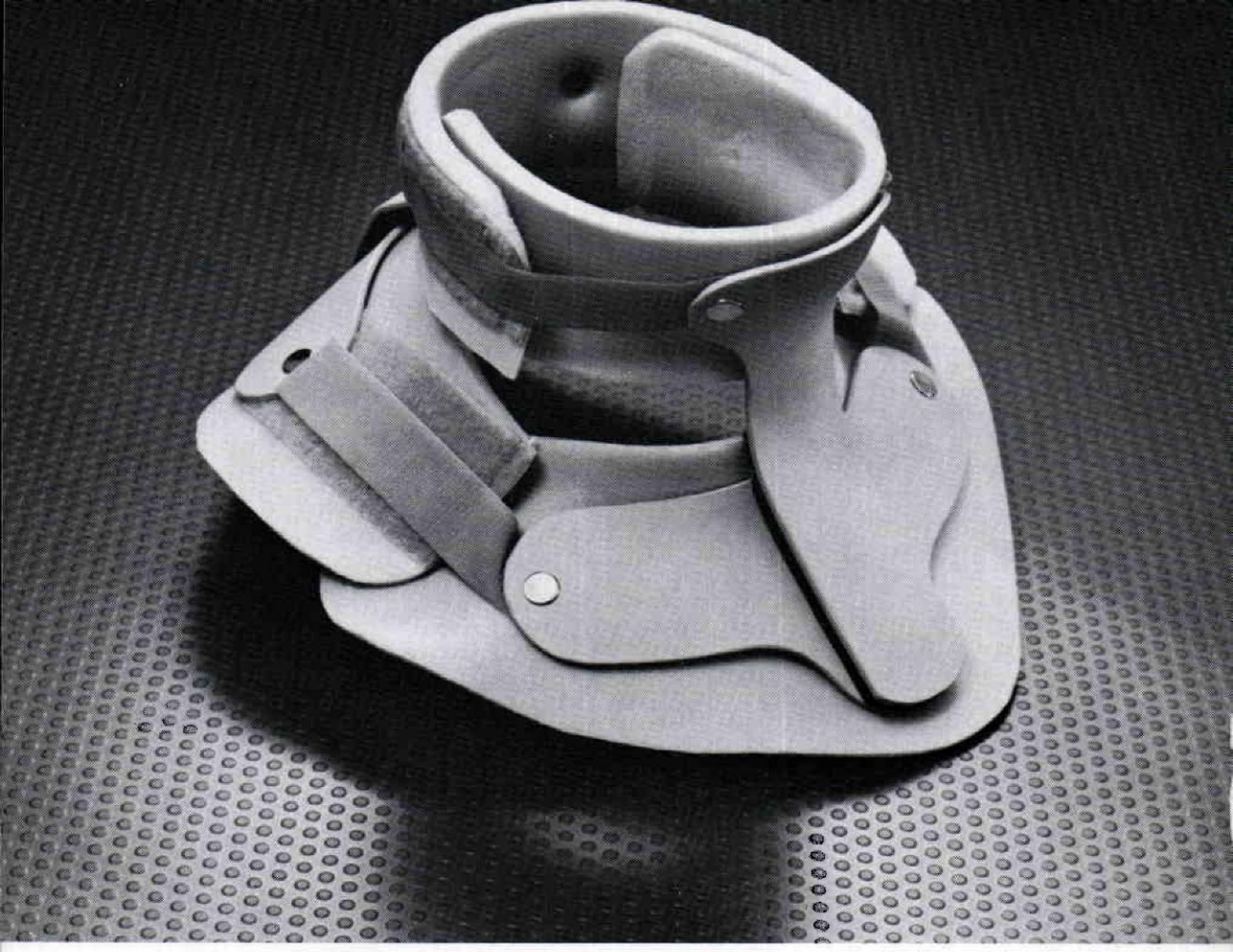

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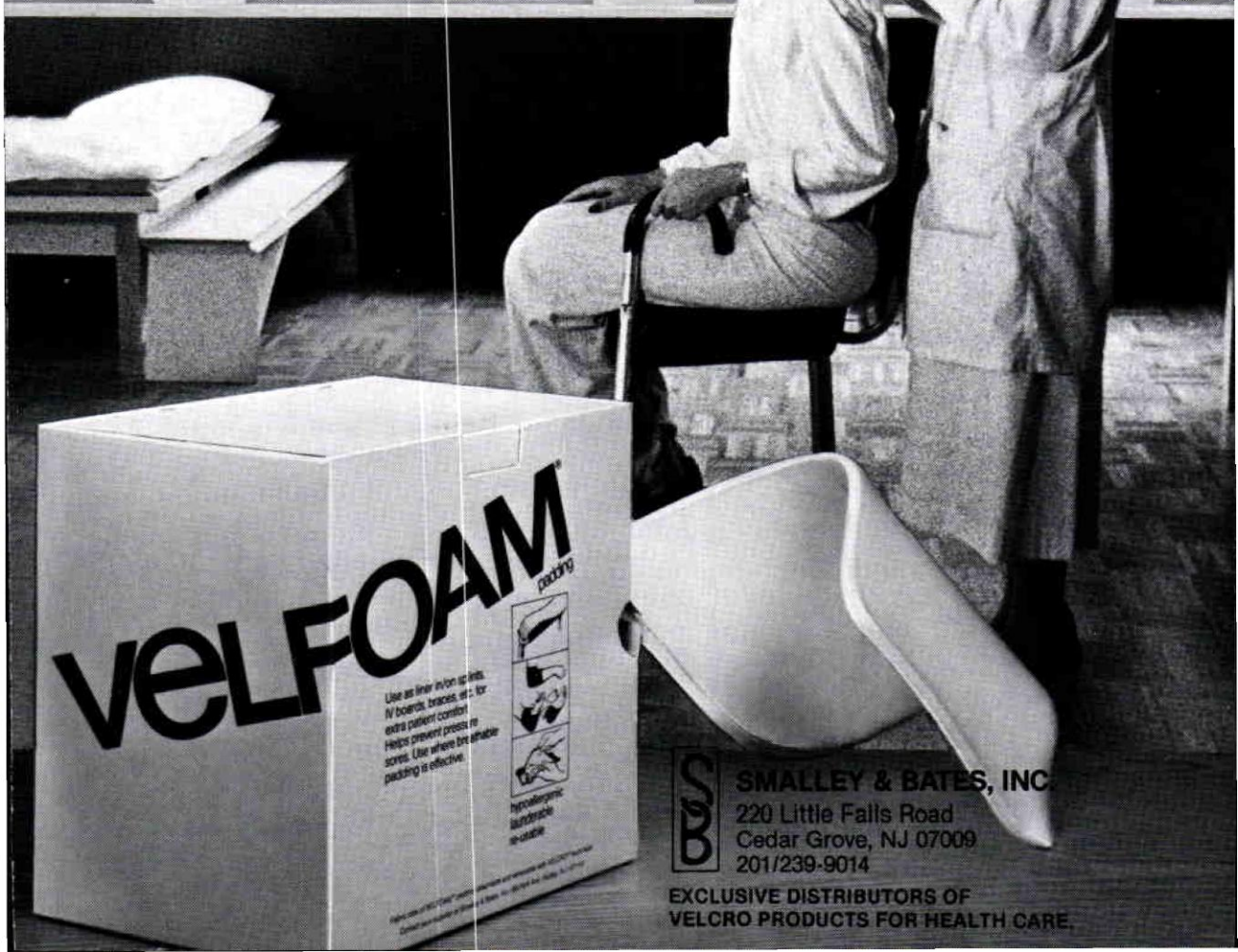

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