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orthotics prosthetics

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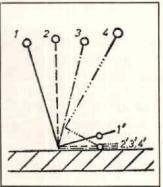
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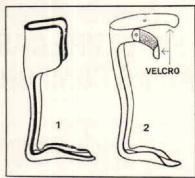


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Fabrication and Application of Transparent Polycarbonate Sockets'

by Vert Mooney, M.D.² and Roy Snelson, C.P.O.²

The potential usefulness of transparent sockets in both research and clinical practice has been recognized for many years. The Navy Prosthetics Research Laboratory used sockets made of Plexiglas in their studies of above-knee fitting during the fifties, and the J. E. Hanger Co. of Atlanta found Plexiglas sockets very useful in their pioneering work with the total-contact above-knee sockets in the early sixties, but fabrication of sockets with this material requires an extraordinary amount of time because it has not been possible to form a socket from a single piece of the material.

The Army Medical Biomechanical Research Laboratory proposed a method of casting a clear socket using an acrylic (2), but the technique required relatively expensive materials and such extreme care for satisfactory results to be obtained that it has not been adopted widely.

New York University later developed a simpler technique for casting transparent sockets with polyester resins (1), but the procedure is sufficiently tedious and time-consuming that it has not been adopted for routine clinical use.

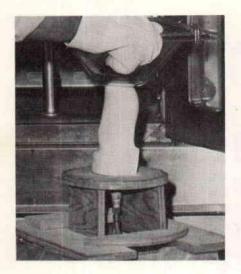
A method of vacuum-forming polycarbonate ³ sheet material has been developed that should make the use of transparent sockets practical in routine clinical practice.

¹ This investigation was supported, in part, by Grant No. 23-P-55290/9 from the Social and Rehabilitation Service, Department of Health, Education, and Welfare, Washington, D.C. 20201. This article is adapted from a progress report made to SRS in November 1971.

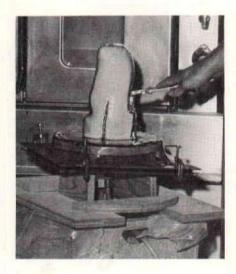
² 7601 East Imperial Highway, Downey, California.

⁸ Supplied by General Electric as Lexan. Other suppliers use other trade names.

THE PROCEDURE



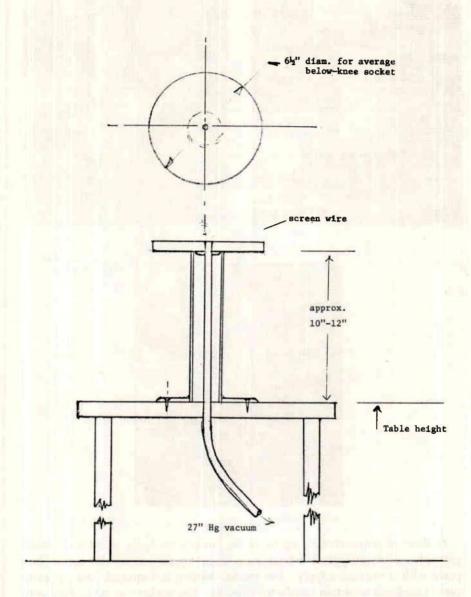




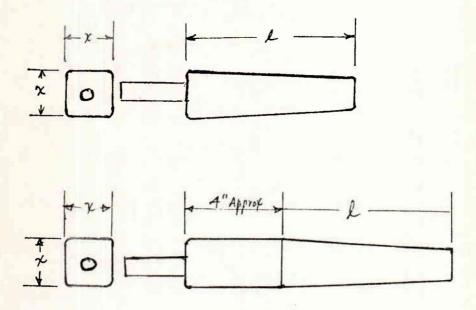
A sheet of polycarbonate up to 3/8-in. thick, after being dried and heated properly, is simply pulled over a male model of the stump and drawn into place with a vacuum supply. No special tooling is required, and no extra care is required to obtain satisfactory results. The socket can be worked with ordinary tools, can be bonded readily, and is sufficiently strong for use in most prosthetics applications. Some of the properties of polycarbonate sheet are given in Appendix A.

A step-by-step procedure for fabrication of a below-knee socket is set forth in the following sections.

EQUIPMENT REQUIRED



No special equipment is required other than a workstand that will support the male model so that vacuum can be applied during the forming process.

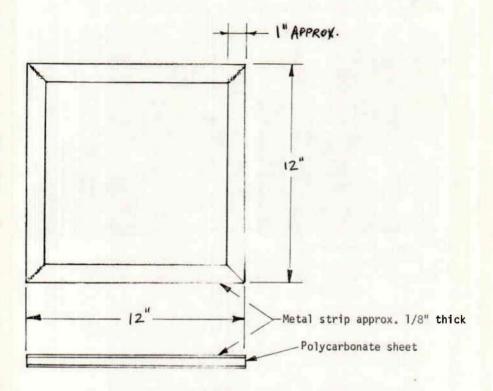


TAPERED MANDREL

Make from wood--cover with two layers of plastic laminate

Vary cross-section dimensions (x) and length (ℓ) to provide a range of sizes

In order for the vacuum to exert sufficient force over the surface of the male model, a removable mandrel is used when the male model is cast, and small holes are drilled between the outer surface and the cavity formed by the mandrel. Mandrels used in the development project were tapered segments with a square cross section and were made from wooden 2 x 2's. They were covered with two layers of plastic laminate to facilitate removal and to provide for increased life.



To permit proper handling of the polycarbonate sheet when heated, it is necessary to hold it in simple metal frames. Strip metal about ½-in. thick and inexpensive "C" clamps were used in the development program.

STEP-BY-STEP PROCEDURE

PREPARATION OF MODEL



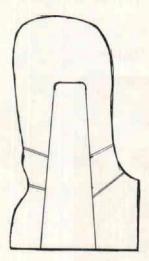


Take a cast of the stump in the usual manner. Pour a male model, using a mandrel to provide the cavity necessary for passage of air during the molding process, and modify as desired. Vaseline or some other parting agent such as "Slipicone" is used on the mandrel. Ordinary plaster-of-Paris may be used, but it is better to use a plaster type that can be heated to 500°F without fracturing.⁴



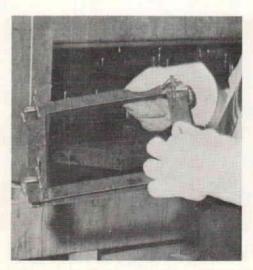
Remove the mandrel, provide a flat surface over the proximal end by sawing or filing to provide a good base for the male model during the molding phase.

^{&#}x27;Easy Out Plaster, 1516 Coolidge St., San Diego.



Drill air passages in the undercut areas from the outside surface to the cavity formed by the mandrel. A steel wire approximately 1/16-in. in diameter makes a good drill.

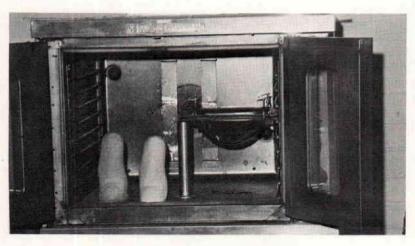
PREPARATION OF THE POLYCARBONATE SHEET



Place a 12 in. x 12 in. sheet of polycarbonate in the metal frames. Material 3/8-in. thick is satisfactory for most adults. Material 1/4-in. thick should be used for children and lightweight adults.



Heat the 3/8-in. material for 36 hours at 275-300 deg. F. to drive out the moisture absorbed by the polycarbonate. If the water is not removed the resulting socket will contain bubbles. It must be maintained at a temperature well below the melting point. A pizza oven was used quite satisfactorily in the development program.



Elevate the temperature to 400 deg. F. until the sheet sags under its own weight to a depth equal to about ½ the length of the male model. This requires about 10-15 minutes. It is desirable to use another preheated oven. The male model is placed in the 400 deg. F. oven at the same time or slightly before the polycarbonate sheet. A heated model allows the prosthetist more time in forming the socket.

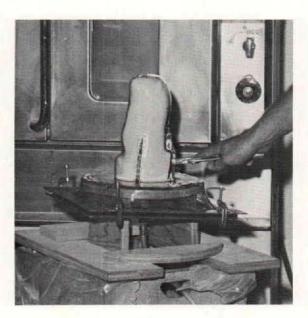
FORMING THE SOCKET







Place the heated male model on the stand. Drape the material still in the frame over the male model, push downward until the polycarbonate contacts the plywood base supporting the male model, and apply 27" Hg vacuum. (Even better results seem to be obtained when the frame and material are turned 180° about the horizontal axis, eliminating the invagination process. It is felt that there is less tendency for formation of built-in stresses when this procedure is used.)



If webs form at the base, use pliers to pinch the sides together so that the inner surface is smooth.

FINISHING THE SOCKET



When the socket has cooled to the point where it can be handled easily, remove it and the cast from stand (this is only a matter of minutes). Remove the plaster, usually by knocking on the outside of the socket with a rubber hammer. The larger the mandrel used, the easier this step is.



Use a cast cutter to remove most of the material proximal to the trim line of the socket.

10



Trim proximal border using band saw and buffer.







Socket is bonded to a Lexan disc approximately one inch thick—four inches in diameter. Using a burr on the router, a cavity is made to accept the end of the socket. A three-part cement ⁵ is mixed and poured into the cavity of the mounting block. The socket is held in slight flexion and adduction until the cement sets. The mounting block is then drilled and tapped and the pylon is screwed to it.

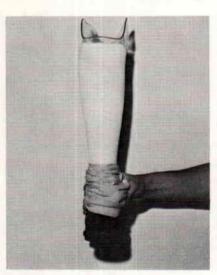
⁵ Cement PS-18 available from Industrial Polychemical Service, 17116 South Broadway, Gardena, California.

APPLICATIONS





Dynamic alignment is carried out.





A cosmetic cover and hose are applied.

REFERENCES

Grille, Thomas, Ronald Lipskin, and Richard Hanak, The NYU transparent socket fabrication procedure, Artif. Limbs, 13:2:13-30, Autumn 1969.
 Margetis, Peter M., Walter L. Shepard, Robert E. Plumb, and Fred Leonard, A fluid resin technique for the fabrication of check sockets, Orth. and Pros., 22:4:8-27, December 1968.

APPENDIX A

PROPERTIES

Parts properly fabricated from the LEXAN 9500 series will exhibit these properties:

| | Property | Average Value | A.S.T.M.
Test |
|---|--|---|---|
| Impact strength, notched Izod, Impact strength, unnotched Izo Tensile-impact, S-type specime | Odor
Taste | 1.20
None
None
1.586 | D 792
—
—
— |
| | Rockwell hardness Abrasion resistance, Taber abraser with CS-1 Impact strength, notched Izod, 1/8-inch speci Impact strength, unnotched Izod, 1/8-inch speci Tensile-impact, S-type specimen | men 14 ft-lb/in. of notch | D 785
D 1044
D 256
D 256
D 1822 |
| | Tensile-ultimate strength
Tensile modulus
Elongation | 9,000 psi
9,500 psi
345,000 psi
90%
12,500 psi | D 638
D 638
D 638
D 638
D 695 |
| | Flexural strength
Flexural modulus
Shear-yield strength | 345,000 psi
13,500 psi
340,000 psi
6,000 psi
10,000 psi | D 695
D 790
D 695
D 732
D 732 |
| | Modulus of rigidity
Deformation under load, 4000 psi 77 F
158 F | 0.37
116,000 psi
0.2%
0.3% | D 621 |
| | Fatigue endurance limit (Krause method),
1800 cycles/min., 73 F, 50% RH | 1,000 psi | |
| | Light transmission (1/8-inch thick disk) Water absorption, 24 hour immersion equilibrium 73 F | 85%
0.15%
0.35%
0.56% | D 570 |
| Thermal
Properties | Thermoforming shrinkage .00 Thermal conductivity 4.6 | 4 psi: 275 F; 66 psi: 285 F
07009 in./in.
6 × 10 ⁻⁴ cal/sec/cm ² /°C/cm
02255 BTU/sec/ft ² /°F/in | D 648
D 955 |
| | Coefficient of linear-thermal expansion 3.7 30 C to 30 C Flammability Se | 75 × 10 ⁻⁵ in/in/°F
7 × 10 ⁻³ in/in/°C
If-extinguishing
low −135 C | D 696
D 635
D 746 |

The Polypropylene Solid-Ankle Orthosis†

John Glancy, C.O.*

Richard E. Lindseth, M.D.**

For many years, the bracing of paraplegic patients has been a discouraging problem to the orthotist. The marked increase in the number of children paralyzed by myelodysplasia has compounded the orthotist's problems, for with these patients, growth is a complicating factor while their potential to walk is generally greater than is the case with other types of paraplegics.

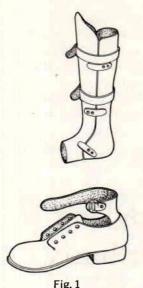
Approximately one quarter of the children with myelodysplasia are paraplegic from the L3-4 level, and therefore have active hip flexors and knee extensors. However, they are not able to walk with conventional bracing as well as one might expect. Despite the use of crutches, their gait becomes progressively worse as they grow older, and their balance becomes more perilous.

The myelodysplastic child, flail from the knees down, can be compared, in one sense, to the bilateral below-knee amputee. When fitted adequately the bilateral BK amputee ambulates very well even though proprioception and peripheral sensation are absent. If the same principles that make the bilateral BK's performance possible were applied to myelodysplastic patients, could not their ambulation

* Chairman, Division of Orthotics, Department of Orthopaedics, Indiana University Medical Center, and Assistant Professor of Orthopaedics, Indiana University School of Medicine.

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Initial Design of the Solid-Ankle Orthosis.

be improved? Attempts to answer this question are reported in this paper.

THE DESIGN PROCESS

The initial design (Fig. 1) consisted of a two-piece molded plastic laminate (polyester) with stainless steel retention bars to "lock in" ML stability. This design was successful in providing stabilization needed for improving balance, and in improving the gait of the first youngster fitted, a seven-year-old boy who wore the orthoses for eleven months without incident before outgrowing them. Later, with other patients, the following problems arose:

- Some of the children and parents had difficulty in applying the bi-valved shells without unwittingly pinching the skin.
- Fabrication of the bi-valved shells required an excessive amount of time because of dif-

- ficulty encountered in aligning the retention bars.
- 3. The shoe tended to migrate laterally as the patient walked.

In an attempt to simplify the fabrication technique, and at the same time make the orthosis easier to don, a one-piece laminate consisting of a modified rigid anterior shell and a flexible calf cuff was devised (Fig. 2) and tried. A Velcro closure fastened to the shoe and passing over the instep replaced the cosmetically objectionable posterior tee strap used in the original design.

Several weaknesses showed up in the second design:

- Failure of the patient or parent to fasten the instep strap securely permitted the exposed heel to move up and down against the back of the shoe, and caused ulcerations.
- 2. The distal edge of the anterior portion of the shell pressed downward on the instep as the weight of the body pressed against the proximal end. This action resulted in a shearing



Fig. 2
The Second Design of the Solid-Ankle Orthosis.

effect, and caused an ulceration across the instep.

The instep strap did not prevent the more active child from walking out of the shoes. It was also cosmetically objectionable, because of the bulk over the instep.

The anteroposterior "rocking" action of this design with its resulting skin breakdown over the instep is related to the fact that it is quite impossible to cast a flail foot in a position of weightbearing and at the same time maintain an optimum position of balance. Therefore, allowance for compression of the foot during weightbearing had to be "guesstimated" when preparing the positive model. A cleaner design was clearly necessary.

It now became evident that the most practical design would have to be foolproof in terms of the device being applied day after day by either patient or parent. It was also evident that complete encasement of the foot, top and bottom, was not



Fig. 3

Present Design of the Solid-Ankle Orthosis: Polypropylene Shell with a Plastazote Lining.

practical. Needed was a shell that could be donned easily and worn only as intended. The present design (Fig. 3) functions well and meets these criteria.

Other factors which influenced the overall configuration of the present design are:

The superior-anterior border of the solid-ankle (SA) shell is located at the level of the tibial plateau for two reasons: 1) to control unwanted AP tibial motion by providing a lever arm equal to the length of the tibia, and 2) to avoid any impingement upon the knee joint.

The vertical length of the anterior panel is related to the patient's weight—the heavier the patient, the longer the panel; i.e., sufficient surface area should be provided to keep pressure on the skin under 7½ psi. to avoid skin breakdown.

The width of the anterior and posterior cutouts are determined by the diameter of the malleoli and relate solely to the application and removal of the shell.

The superior border of the posterior portion, and the space between it and the inferior border of the anterior panel are explained in the section on TRIM-LINES.

The width of the side panels, at ankle and heel levels, are kept as broad as possible to provide strength for resistance to pressure from the body against the anterior panel in the AP plane. Obviously, the width of these panels is also influenced by the diameter of the malleoli; i.e., the width of the anterior cutout.

The degree of the slope given to the side panels of the foot portion of the shell at their distal ends is determined by the depth of the vamp of the shoe. Material is removed gradually until the shell can be slipped into the shoe with ease.

Ending the bottom distal edge at the metatarso-phalangeal joints is a compromise in order that commercial shoes can be used Even if custom made shoes were used and the bottom of the shell was continued to provide a complete inner sole, AP alignment (as described under SHOE MODIFICATIONS) would be totally dependent upon the casting technique, and would make casting and fitting even more difficult.

In an effort to determine the order of importance of various clinical observations, 16 mm motion pictures were taken of several spina bifida children. The films were slowed to 2 frames per second and the children's gaits were studied individually. The gaits of both crutch and non-crutch walkers were analyzed. The walking patterns of the non-crutch walkers were the most revealing. The youngsters without crutches must keep their legs and feet in constant motion in order to maintain their balance, whether or not they wear conventional bracing. Their bilaterally flail feet are 'converted', as it were, to ball-andsocket-like joints about which their tibiae roll continually and uncontrolled. Add to this the fact that these children lack the sensory perception to know where their feet are at any given moment, and it becomes apparent that positive control of this 'out-of-phase' motion of the tibia is the first order of business. The films were helpful in making it possible to identify other specific features of these pathological gaits. Further work in these areas is now in progress.

Prior to August 1970, all of the shells, including the present design, used polyester laminations. Except for the initial design (Fig. 1), all laminations used were inadequate in strength, becoming warped and distorted in a short time despite liberal reinforcement with glass cloth, fiberglass roving, and woven polypropylene cloth. The distortion allowed unwanted motion of the foot within the shoe, causing pressure sores over bony prominences. Attempts to eliminate the distortion led to heavier, thicker shells which were unacceptable because of shoe fitting and cosmesis problems. Since molded polypropylene was substituted for the plastic laminate problems of distortion have been virtually eliminated.

All shells are now being lined with ½ in. thick Plastazote which seems to decrease the possibility of sores, especially when friction, rather than pressure, is suspected to be the cause. Observations made of the gaits of myelodysplastic children, with and without the SA orthoses, provide the basis for the suspicion that friction is also a problem.

Although it has been stated that polypropylene has eliminated the problems of distortion, it is not intended to imply that the SA shells made of polypropylene remain completely inflexible when subjected to

the torques which these pathological gaits generate. Quite the contrary. The ability of polypropylene to yield to these forces, within ranges dictated by a given gait, yet consistently return to its original form without fatiguing, has eliminated distortion.

Examination of the twisted laminated shells made it apparent that the children were attempting to rotate their tibias externally while wearing the SA orthoses, and that they must be generating quite high torques in the transverse plane while walking. Evidently, the laminated shells would not yield until they fatigued. It seems reasonable to assume that the tibia, in or out of the shell, is the least able to resist the torque and, therefore, when in a laminated shell, the malleoli would rub against the non-yielding material surrounding it. The polypropylene 'follows' the tibia as it rotates externally with each step. At the same time the polypropylene shell's two side panels are turning about the vertical axis of each panel, and displacement between the malleoli and the shell is reduced. However, it cannot be totally eliminated. The Plastazote appears to absorb the residual displacement between the leg and the shell and keeps the malleoli from rubbing against the polypropylene. The Plastazote lining is too thin to act as a resistance to pressures caused by poor anatomic alignment or to a shell which is either too tight or too loose. Its use is not related to control of motion.

CLINICAL EXPERIENCE

Since August 1970, 58 cases have been fitted with the third design using polypropylene. Of these,

52 were bilateral and 6 were unilateral. The patients' ages range from one year and 5 months to 67 years. There were 33 females and 25 males. The group includes 47 with spina bifida, 4 who are traumatic paraplegics, 2 with head injuries, 2 with transverse myelitis, 2 with club foot and one suffering from a cerebral vascular accident. Seven of the group required polypropylene thigh cuffs attached to the SA shells with conventional metal lateral uprights and knee joints.

The feet of spina bifida patients present fitting problems unlike other paraplegics. Although the majority of the L3-4 patients present a valgus hindfoot accompanied by prothe forefoot during nation of weightbearing, because they are growing children bony deformations which are not always evident when standing occur often. The orthotist must be able to recognize and accommodate for several conditions which may appear while he is attempting to place such feet in the optimum standing position for casting. If the relationship of each condition to optimum control of motion of the foot-ankle complex is not understood, a high percentage of failures is inevitable.

CASTING TECHNIQUES

Casting techniques vary somewhat with respect to the functional condition of the feet.

When both feet are supple

If the patient's feet are supple and little or no resistance is encountered when each foot is passively brought into the optimum position of balance, the casting technique is as follows: The apices of the malleoli are marked on the skin. A mark is placed ½ in. below the head of the fibula and anteriorly at the level of the tibial plateau. Marks are placed on the skin every two inches between the apex of the lateral malleolus and the mark ½ in. below the head of the fibula.

Linear measurements are record-

- 1. The apex of the lateral malleolus to the mark ½ in. below the head of the fibula. (Identification of the head of the fibula serves as a guide for determining the lateral proximal trim line.) Pressure upon this thin-skinned area must be avoided.
- 2. The proximal, superior surface of the instep to the mark at the level of the tibial plateau which will be the proximal anterior trim line.
- 3. A Ritz stick is used to obtain the width between the medial and lateral borders at the ball of the foot. This measurement is taken with pressure upon the forefoot to simulate the condition imposed by a laced shoe.

Circumferential measurements are recorded for each 2 in. increment.

A double layer of tube gauze is pulled over the foot and leg. A length of rubber tubing is placed along the parasagittal line for protection when the cast is cut for removal later. Two layers of elastic plaster bandage are wrapped from a point distal to the ball of the foot to approximately 1 in. proximal to the tibial plateau. A single layer of extra-fast-setting plaster bandage is added.



Fig. 4

A navicular pad (shown in readiness) is inserted under the longitudinal arch between the wrapped foot and the footboard and held in place while the plaster is setting.

The seated patient's foot is then placed on a flat board, and is checked to be sure its AP relationship to the tibia is 90°. While the plaster is setting, the orthotist must maintain the foot in an optimum medio-lateral position by holding the heel in the neutral position and pressing downward on the forefoot to approximate the pressure of a firmly laced shoe. The longitudinal arch is maintained by placing a rubber navicular pad* between the and the board (Fig. cast Throughout the holding procedure, care must be taken to be sure that the tibia remains vertical over the foot while the cast is setting. It is often necessary to have either the patient or an assistant grasp the knee to ensure correct tibial alignment until the cast is sufficiently set for removal. The use of warm water and the extra-fast-setting outer layer

^{*} Rubber navicular pads are commercially available in various sizes.

of non-elastic plaster bandage help to reduce the holding time.

When "correction" results in forefoot supination

Though the patient may present an everted heel accompanied by severe pronation when standing, the position of the forefoot in relation to the hindfoot may not be the same when the os calsis is passively placed in the neutral position. If bony deformation, i.e., wedging, has occurred, the forefoot will be in *supination* when the heel is held in an optimum position of ML balance.

In such cases, the degree of supination present must be accepted and special care must be given to the exaggerated space between foot and board in the area normally considered the longitudinal arch. This space must be fitted with a suitably steep sloping navicular pad before casting. Once this pad is shaped, it is inserted between the cast and the footboard, as described in the casting procedure above. This will en-

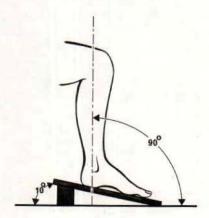


Fig. 5

An example of the positioning of the leg and foot when equinus must be accepted to achieve optimum balance in the M-L plane.

sure that weight can be borne along the medial border without the foot reverting to pronation when standing in the orthosis. Failure to accommodate for this condition at the time of casting will result in ulcerated sores over both the medial malleolus and the navicular bone.

When there is fixed equinus present

With the heel in a fixed position of equinus, the foot cannot be brought to neutral in the AP plane without the heel (which takes the forefoot with it) rolling into valgus. The orthotist must note the point at which the heel begins to roll laterally as he dorsiflexes the patient's foot. This "trigger" point indicates the amount of equinus which must be accepted to ensure optimum ML balance. It usually occurs between 5 and 15° of equinus, i.e., 5 to 15° short of the sole of the foot being 90° to the tibia. To allow for the fixed equinus, the footboard is raised at the heel end to a degree equal to the fixed equinus heel (Fig. 5). The cast is then applied as described previously. Care must be taken to see that the tibia is perpendicular to the floor, not the inclined footboard.

It is necessary that both feet be cast in the same degree of eqinus in order to provide optimum control of AP balance to the patient. When one foot has a fixed equinus heel and the other has not, the foot which has no fixed equinus must be cast in a position of equinus equal to that of the other foot. When both feet present different degrees of fixed equinus, both feet are cast in the position of the one with the greatest amount of equinus.

When a calcaneal deformity is present

Occasionally a child will have a marked calcaneal deformity owing to contraction of the pretibial muscles without opposition to the paralyzed triceps sura muscles. Weightbearing over a period of time may cause the calcaneous to rotate downward and backward.

The abnormal posterior rotation is usually fixed and must be accepted. When casting such a foot it is important to hold the forefoot on the footboard while an assistant applies pressure upon the anterior aspect of the knee in order to obtain an AP relationship between the foot and the tibia as near to 90° as circumstances will permit. The SA shell combined with a snugly laced shoe will maintain the alignment obtained in the cast.

Some spina bifida patients with calcaneal gaits may have had repeated ulcerations on the bottoms of their heels due to excessive pressure, and so much tissue has been destroyed that there is no semblance of a heel contour left. In such cases, a normal heel contour must be added to the positive model to prevent the patient from walking out of his shoes. Silastic foam is used to fill the hollow between the shell and the hindfoot.

When the heel is in fixed valgus

When the os calsis cannot be brought into the normal ML weight-bearing alignment, ulcerated sores are likely to develop about the medial malleolus and the navicular bone. If surgical correction of the deformity cannot be made, the foot is cast in the best position possible

and extra padding is incorporated within the orthosis to prevent skin breakdowns in the areas mentioned.

THE POSITIVE MODEL

The negative cast is cut along the rubber tube, removed and sealed, and a positive mold is poured. The positive model is carved to the circumferential measurements. Reliefs for the malleoli and any other bony prominences which have been noted, are carefully placed and bonded to the model.

FORMING THE SA SHELL

The modified positive model is placed in a vise, heel end up. A coat of shellac and a single layer of cotton stockinette are applied. The stockinette compensates for the space needed for the patient to wear a stocking within the shell. Should, for some reason, a Plastazote lining not be used the stockinette must be covered with talcum powder to prevent the hot polypropylene from sticking to it.

Rectangular pieces of Plastazote and polypropylene are cut to a size two inches longer than the length of the model from its posterior proximal edge, over the back of the heel, to its distal edge on the plantar aspect of the foot and two inches wider than the largest circumference of the model. The Plastazote lining is ½ in. thick. The polypropylene is usually 3/16 in. thick, though ½ in. is sufficient for small toddlers and ¼ in. may be necessary for heavy individuals.

The Plastazote is heated in an air circulating oven for 5-6 minutes at 285°F. Two technicians are needed to form both the Plastazote and the



Fig. 6
Plastazote Formed Over Model.

polypropylene. The working time for both materials is short, though manageable when two individuals work as a team. The working time for the Plastazote is approximately ½ minute; for the polypropylene, 1½ to 2 minutes. Should the Plastazote stabilize before forming is completed or an error in the placement is made, it can be reheated whereupon it will return to its original sheet form ready for reuse. Polypropylene is made of "sterner stuff" and cannot be reused.

Once the Plastazote has been formed to the model, excess material is trimmed away and the formed lining is secured to the model with scotch tape along its anterior trim line. (Fig. 6.)

The polypropylene blank is placed in the air circulating oven on a tray covered liberally with talcum powder to prevent sticking, and heated for 20-25 minutes at 400°F. When heated to its plastic state, polypropylene is extremely sticky and stretches easily. When a bond



Fig. 7
Placement of Molten Polypropylene Sheet Over Model.

is desired, the unpowdered surface is placed in contact with the preformed Plastazote. If a bond is not wanted, both top and bottom surfaces are powdered before placing the polypropylene in the oven.

Asbestos gloves must be used to handle the material when heated. and they, too, must be powdered to prevent the plastic from sticking to them. When the polypropylene is ready, the tray is removed from the oven, the two technicians lift the blank by its four corners and place it over the model (Fig. 7). Of its own weight, the material will drape itself about the model, and the technicians quickly, yet gently, stretch and smooth the material over the model with their gloved hands. While it is still hot, excess material along the anterior centerline of the



Fig. 8
Trimming Away Excess Material.



Fig. 9 Completed Shell Ready for Trimming.

model is trimmed off (Figs. 8, 9, 10). The form is then wrapped with elastic bandage and allowed to cool.

TRIM LINES (Fig. 10)

The measurement (a) taken from the proximal end of the patient's instep to the tibial plateau is now repeated over the model, and a mark is drawn to designate the proximal end of the shell anteriorly. The length (c) of the anterior panel of the shell will vary with the size of the patient, usually 4-5 in. for adults and 3-3½ in. for children, A diameter measurement (d) is taken obliquely from the proximal end of the instep to the apex of the back of the heel. One-half inch is deducted from the diameter measurement (d) and the remainder determines the size of the opening from

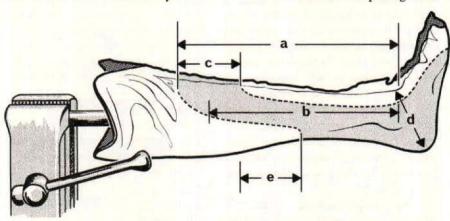


Fig. 10 Trimlines

a, from proximal end of instep to tibial plateau; b, apex of lateral malleolus to ½ in. below fibula head; c, from tibial plateau, 3-5 in., depending on length of leg; d, diameter, from proximal end of

instep to apex of heel; e, proximal edge of posterior panel—diameter, d, less ½ in. from lower edge of anterior panel. Dotted lines show anterior/posterior cut-outs.

back to front through which the foot must pass to don the shell (e) and thus defines the proximal border of the posterior trim line. These three marks, designating the top and lower edges of the front panel and the top edge of the back panel, are then connected together (care being taken to avoid the fibula head, b) to produce the design shown in Figure 3. A Stryker cast cutter is used to cut the open anterior and the upper posterior areas of the design. The anterior panel is then cut along its center line where the ends of the blank had been drawn and stuck together during the forming. The shell can be spread and removed from the mold. The Plastazote lining, which has now adhered to the inner surface of the polyproyplene shell, is peeled back from the vertical sides of the anterior panel. The vertical edges are beveled, butted together and welded by using a special electric gun* in which heated nitrogen is used to fuse polypropylene welding rod to the seam. The distal edge of the foot portion of the shell is immediately proximal to the first and fifth metatarsophalangeal joints. All edges are sanded with a highspeed sander to bring the rough cut to the finish lines of the design, as shown in Figure 3.

Very little final trimming is necessary if the suggested trim lines are observed. A heat gun may be used to reshape the edges when necessary. All edges are sanded smooth, a strip of ½ in. Plastazote is beveled and cemented inside to

cover the vertical seam of the lining along the weld line. A 2-inch wide Velcro closure is attached, posteriorly (Fig. 3).

THE SHOE

High-top shoes are not necessary. A conventional laced oxford is generally used for children and the lightest weight laced oxford available (such as "Hush Puppies") is recommended for the adult traumatic paraplegic. Experience has proved that it is not necessary to delay fitting the patient with shoes until the SA shells are completed. Shoes one and one-half sizes longer and two widths wider than the patient's regular size provide adequate accommodation for the shells.

SHOE MODIFICATIONS (Fig. 11)

A full-length metal shoeplate is incorporated into the shoe to augment the overall control function of the SA orthoses. The shoeplate prevents out-of-phase motions of the

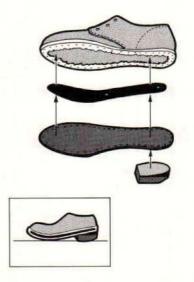


Fig. 11 Shoe Modifications

^{*} Kamweld Highspeed Welder, Model 10-HS, 650 watt heating element and special welding tips which hold the welding rod.

flail MP joints whenever the body's center of gravity moves anterior to the lateral midline. In essence, its function mimics that of the forefoot portion of a prosthetic foot. Since the shoeplate prevents the shoe from flexing, its resistance to floor reaction forces also prevents the anatomic forefoot from jamming into the shoe and causing ulcerations along the 'flexion crease' which normally forms across the top of a shoe. It is much easier and cheaper to provide control of the MP's in the shoe than to incorporate such control into the shell.*

The heel and complete sole of a conventional shoe are removed, and if the shoe has a steel shank, it, too, is removed. Rubber cement thinner is used to remove the entire crepe sole and heel from the uppers of light-weight shoes. The bottom of the shoe's upper is traced and the pattern is reduced 3/8 in. to 1/2 in. all around. The modified pattern is traced onto the surface of a sheet of hot roll 40/50 carbon steel (either 14, 16 or 18 gauge, depending on the size of the patient), cut out and sanded. The toe end is bent upward for toe clearance. The rest of the shoeplate, from the apex of the ball of the foot to the end of the heel portion, is left flat. Two holes for copper belt rivets are drilled into the plate, one at the heel and the other approximately in the middle of the longitudinal arch area. An acetylene torch is used to heat the plate to a dull red color and then quenched in water to temper. The plate surface is sanded lightly to remove discoloration caused by the heat, reheated to a blue color, and quenched in water for the second time. Care should be taken, when quenching the plates, to submerge them in the water slowly, toe end first, to prevent warping. The plate is cemented to the bottom of the shoe upper and riveted, thus flattening its longitudinal arch portion to the plate. The sole is stitched or cemented (depending on the type

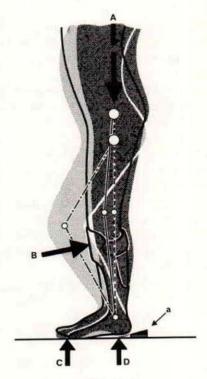


Fig. 12

A-P Balance: Spina Bifida, L3-4 Level. Darkly shaded figure represents normal posture. Lightly shaded figure is without orthoses. Solid black line is with SA shells. A, body's weight; B, counterforce; C, floor reaction force to forward motion; D, floor reaction force to backward motion. C plus D equal A, when standing. Small letter "a". resists counterforce, B, by maintaining knee flexion when standing. Note that excessive lordosis cannot be fully eliminated.

^{*}A metal shoeplate was used, from the beginning, for all the shell designs previously described.

of shoe being used) back onto the upper.

The trimmed shell is inserted in the shoe, which is placed on a level surface, and the heel portion of the shoe is lifted until the vertical edge of the anterior panel of the shell is 3-5° anterior to a line perpendicular to the level surface. When this alignment has been reached, a measurement is taken from the back of the heel to the level surface. A lightweight nuron crepe heel is built on the shoe to the measurement and tapered toward the toe. The usual rounded back portion of the crepe heel is sanded flat at an oblique angle in the anterior-posterior plane to prevent transverse, medio-lateral wobble and to provide a more natural "roll" at heel-strike. This heel setting accomplishes two things:

- 1. It forces the knee into slight flexion in stance phase which is necessary for these patients' AP balance, since hip flexion contractions and excessive lordosis (which are common to them) cannot be fully reduced (Fig. 12).
- 2. It prevents the reaction force

of the anterior panel from forcing the knee into recurvatum (Fig. 12).

SUMMARY

A single unit, lightweight (6-12 ounce) plastic BK shell that provides control of the foot/ankle complex in all three planes and the knee in the AP plane has been described. The design is based on biomechanical principles embodied in modern prostheses. Hence its name, SA orthosis, denotes it to be an 'orthotic counterpart' to the SA prosthesis and also denotes its function, i.e., the mechanical control of 'out-ofphase' motion of the ankle and foot. The intimate fit of the SA shell provides control of action superior to that which can be obtained with conventional BK braces. In essence, the shell supersedes the function expected of a shoe in combination with conventional BK bracing. For this reason, a much lighter weight, laced oxford is adequate when modified to complement the shell's biomechanical function.

The casting, fabrication and shoe modifications for the polypropylene SA orthosis are presented in detail.

A Clinical Evaluation of Four Lower-Limb Orthoses*

Maurice A. LeBlanc, C.P.**

In recent years there have been many new developments in lower-limb orthotics. On March 9-12, 1970, the Committee on Prosthetics Research and Development of the National Research Council sponsored a workshop on lower-limb orthotics (2) where nineteen different designs were presented, demonstrated on patients, and discussed. As a result of that meeting and subsequent meetings of the Subcommittee on Evaluation, a clinical evaluation of the four orthoses listed below was undertaken in late 1970.

** Staff Engineer, Committee on Prosthetics Research and Development, National Academy of Sciences—National Research Council. University of California Biomechanics Laboratory (UC-BL) Shoe Insert

New York University (NYU) Insert Orthosis

UC-BL Dual-Axis Ankle Orthosis Veterans Administration Prosthetics Center (VAPC) Single-Bar Above-Knee Orthosis

The following seven clinics were selected originally to participate in the evaluation project:

NYU Prosthetics and Orthotics Northwestern University Prosthetic-Orthotic Center

Rancho Los Amigos Hospital
Texas Institute for Rehabilitation
and Research

University of California at Los Angeles Prosthetic - Orthotic Program

University of Miami Department

^{*} Adapted from Report E-5 of the Committee on Prosthetics Research and Development, National Academy of Sciences. This work was supported by the Social and Rehabilitation Service, Department of Health, Education, and Welfare under the terms of Contract SRS-71-8.



Fig. 1 UC-BL Shoe Insert.

of Orthopedics and Rehabilitation

VAPC Patient Service Clinic

The VA Hospital in West Los Angeles was added later to the list of participating clinics. NYU and VAPC were not involved in evaluation of the orthoses developed in their own organizations.

UC-BL SHOE INSERT (Fig. 1)

Purpose

The UC-BL shoe insert was designed to hold the foot in position of function in the shoe. It was developed originally to control the foot when fitting the UC-BL dual-axis ankle-control system. (4).

Description

The shoe insert is a laminated plastic shell that is contoured to the foot. The insert accomplishes its purpose by stabilizing the foot in a position of proper alignment. It can be used without a brace or a brace may be attached to it (p.).

Prescription

The UC-BL shoe insert is used to provide correction of nonrigid

varus and valgus deformities of the subtalar joint, for painful subtalar joint motion secondary to arthritic changes, and for inflammation of the plantar fascia. It is contraindicated when fixed bony deformities exist.

Fabrication

The general procedure is that a plaster cast is taken of the foot with weight-bearing, and the shell is laminated over the plaster male model. The fabrication of the shoe insert is covered in detail by Henderson and Campbell. (3).

NYU INSERT ORTHOSIS (Fig. 2)

Purpose

The NYU insert orthosis combines the advantages of the UC-BL shoe insert (4) with the conventional below-knee brace to stabilize the foot in the shoe while providing control of motion about the ankle joint. At the same time cosmesis is improved and interchange of shoes can be made easily because no connection to the shoe is required.



Fig. 2 NYU Insert Orthosis.

Description

The insert orthosis is a conventional below-knee orthosis with the metal stirrup laminated into a shoe



Fig. 3 UC-BL Dual-Axis Ankle Orthosis.

insert that provides alignment of the foot in the shoe. Standard ankle joints provide A-P control of the ankle, and double uprights with a calf band provide M-L stability of the ankle. A slightly larger shoe may be required when the orthosis is used because of the thickness of the insert and stirrup.

Prescription

The insert orthosis is indicated for flaccid or mildly spastic paralysis of the ankle joint musculature, and for nonrigid varus or valgus deformities of the foot. It is contraindicated when severe spasticity or fixed varus or valgus deformity of the foot is present.

Fabrication

A plaster cast is taken of the foot according to UC-BL procedures for the shoe insert (4). The ankle joint

is aligned on the plaster model, and the stirrup is laminated into the plastic shell over the model. The ankle joints and metal uprights with calf band are attached to the stirrup. Fabrication procedures are detailed by New York University (6).

UC-BL DUAL-AXIS ANKLE ORTHOSIS (Fig. 3)

Purpose

The UC-BL dual-axis ankle orthosis was designed to duplicate and control the combined motions of the ankle and subtalar joints in such a way that there is no relative motion between the orthosis and the patient at the points of attachment (4, 5).

Description

The dual-axis ankle orthosis has two mechanical joints—the lower of which attaches to the shoe — with one metal upright which attaches to a calf band. It accomplishes its purpose by alignment of the mechanical joints to the anatomical ankle and subtalar joints, and by using rubberband and spring assists about the joints.

Prescription

The UC-BL orthosis is indicated for flaccid paralysis of the plantar flexors, dorsiflexors, inverters, and everters of the foot.

It is contraindicated when pain exists due to increased ankle or subtalar joint motions or when there are rigid deformities of the ankle or subtalar joints. Also, in its present configuration, it cannot be used where weight-bearing is necessary. (A weight-bearing design is under development.)

Fabrication

The general procedure is to take



Fig. 4
VAPC Single-Bar Above-Knee Orthosis.

a plaster cast of the foot and lower leg and very carefully align the mechanical joints to the cast which is positioned in the shoe. The joints are then attached to the shoe, the calf band is positioned on the cast, and the upright bent and connected to the joints and calf band. Fabrication of the dual-axis ankle orthosis is covered in detail by Campbell et al. (1).

VAPC SINGLE-BAR ABOVE-KNEE ORTHOSIS (Fig. 4)

Purpose

The VAPC single-bar AK orthosis is intended to stabilize the knee and ankle in M-L and A-P directions during stance phase of gait. It is designed to be a light, modular-type orthosis that can be fitted easily (7).

Description

Stability of the leg is provided

during stance by a locked knee. Weight-bearing is not provided. The single-bar construction has the advantage of reducing weight and bulk. The orthosis is comprised of the following components: a half stirrup with ankle joint mounted to the shoe; a lateral, round, stainless-steel upright; a metal calf cuff which extends upward medially to the tibial condyles; a locked knee joint with posteriorly offset center of rotation; and a metal thigh cuff which spirals downward medially to encompass two thirds of the thigh. The cuffs are covered with leather and closed with Velcro. The modular system permits the following: various diameter uprights for strength; posterior or anterior ankle stops; telescoping uprights that accommodate axial and rotational movement; proximal extension of uprights to include the hip joint; and free knee if the patient is able to use it.

Prescription

The VAPC device is indicated for instability of the knee and ankle when functional control of the hip is present. It can be used bilaterally, thereby eliminating both medial uprights present on conventional above-knee braces.

It is contraindicated where there is lack of hip control, fixed deformities of the knee or ankle, need for weight-bearing, or presence of marked spasticity.

Fabrication

Fabrication procedures are similar to those for a conventional aboveknee brace except that the thigh and calf cuffs are shaped and fitted so as to provide appropriate reaction forces on the medial side normally

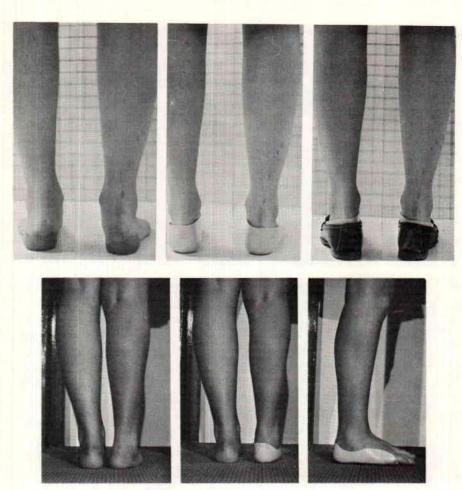


Fig. 5
Some Clinical Fittings of the UC-BL Shoe Insert.

provided by the medial uprights (7).

EVALUATION PROCEDURE

Orientation Sessions

An orientation session was held on August 24-28, 1970 at UCLA for the developers to familiarize clinic teams with the two UC-BL orthoses and for CPRD staff to familiarize clinic teams with evaluation procedure. A similar orientation session was held on October 26-30, 1970, at NYU covering the VAPC and NYU orthoses.

Selection of Patients, Clinical Fittings, and Evaluation Forms

Following the orientation sessions, the clinics returned home and selected patients according to the developers' prescription criteria. The patients were fitted with the new orthoses for a one-month trial-wear period. Before and after this time, evaluation forms were completed by the clinic teams to report the results. The instructions and evaluation forms for this procedure are attached as Appendix A.

Site Visits

The CPRD staff made site visits to all the clinics once during the interim period and once at the completion of the evaluation. When possible, developers accompanied the CPRD staff in seeing patients and talking with the clinic teams. These site visits were valuable in assessing the progress of the evaluation, in resolving minor fabrication and fitting problems, and in supplementing the information recorded on the evaluation forms.

Subcommittee on Evaluation Meeting

A meeting of the clinics, developers, and members of the Subcommittee on Evaluation was held August 5-6, 1971, in Washington, D.C., to discuss the results of the evaluation.

RESULTS

Number of Clinical Fittings

A total of 84 fittings was made by the participating clinics as shown below.

Summary of Clinical Fittings Of the UC-BL Shoe Insert

- 1. Patients: 31 fittings on 21 patients (10 bilateral); 11 male, 10 female; age range 7-78
- 2. Diagnosis: flat feet 5 4 plantar fasciitis 3 polio metatarsal pain 2 arthritis 1 1 weak arches subtalar joint pain 1 hemiplegia 1 talipes cavus 1 talipes varus 1 incomplete quadriplegia
- 3. Patient Preference: 17 preferred this orthosis (11 were previous wearers and 6 were not; 3 did not prefer this orthosis (1 was a previous wearer and 2 were not); 1 indifferent
- Clinic Team Opinions: 17 cases
 —the orthosis was satisfactory; 3 cases—the orthosis was not satisfactory; 1 case—questionable

| Clinic | NYU
Insert
Orthosis | UC-BL
Shoe
Insert | UC-BL
Dual-Axis
Ankle Orthosis | VAPC
Single-Bar
AK Orthosis | Total |
|--------|---------------------------|-------------------------|--------------------------------------|-----------------------------------|-------|
| NYU | | 3 | 4 | .5 | 12 |
| NU | 6 | 9 | 6 | 6 | 27 |
| Rancho | | 4 | 5 | | 9 |
| TIRR | | 0 | 4 | | 4 |
| UCLA | 0 | 6 | 0 | 0 | 6 |
| UM | 6 | | | 5 | 11 |
| VAPC | 6 | | | | 6 |
| VA/LA | | 9 | | | 9 |
| Total | 18 | 31 | 19 | 16 | 84 |

- Main Advantages: relief of pain; proper support of foot
- Main Disadvantages: requires wider shoe in some cases; difficult to fit well; some became loosefitting with wear

7. Remarks:

- a. Of the 3 patients who did not prefer this orthosis
 - 1 (arthritis) rejected because of severe swelling
 - (flat foot) rejected because needed only after a long day on feet
 - 1 (heel spurs) was unable or unwilling to participate in the evaluation
- b. The weight of the orthosis is negligible.
- c. There was a general problem with fitting and trim lines.
- d. Several inserts were successfully modified with metatarsal bars or pads.
- e. Two inserts were used in lieu of ankle-foot orthoses, and three inserts were used with ankle-foot orthoses.
- 8. Recommendations for Improvement of Orthosis:
 - a. A thinner (and stronger) material is needed for the insert.
 - b. It would be preferable to be able to reshape the insert.
 - Eliminate use of turntable stand and use mirror for correction of foot during casting.
 - d. One suggestion was made to bring the insert up and over the instep of the foot with flexible material for greater comfort and security rather than trimming low on the medial and lateral aspects. This technique

might be especially applicable when a stirrup for uprights is to be incorporated into the insert.

Indications and Contraindications:

The insert appears to be a very worthwhile orthosis for a variety of foot conditions. The only contraindication appears to be the presence of fixed bony deformities or swelling.

10. Consensus:

It was the consensus that this orthosis is a most valuable addition to patient service. In order to fit it successfully, however, thorough knowledge of how it works and training in fabrication are necessary.

Summary of Clinical Fittings Of the NYU Insert Orthosis

1. Patients:

18 fittings on 15 patients (3 bilateral)

10 male, 5 female age range 11-59

2. Diagnosis:

| hemiplegia | 5 |
|---------------------|---|
| peroneal nerve loss | 5 |
| paraplegia | 2 |
| arthritis | 1 |
| multiple sclerosis | 1 |
| disc herniation | 1 |

3. Patient Preference:

- 9 preferred this orthosis (6 were previous wearers and 3 were not)
- 6 did not prefer this orthosis (all 6 were previous wearers)

4. Clinic Team Opinions:

- 10 cases—the orthosis was satisfactory
- 4 cases—the orthosis was not

satisfactory

1 case-questionable

5. Main Advantages:

good control of foot and ankle lighter more cosmetic can change shoes

 Main Disadvantages:
 wider shoe required in many cases difficult to fabricate and fit well

7. Remarks:

- a. of the 6 patients who did not prefer this orthosis,
 - 2 disliked it because of the wider shoe needed
 - 2 had fitting problems with insert portion
 - 1 had swelling and pain with insert

1 preferred previous wire brace

- b. Weight: NYU orthosis—average 2½ lb. conventional orthosis—average 2½ lb.
- c. There was a general problem of adequately fitting the insert which is crucial to the success of the orthosis
- 8. Recommendations for Improvement of Orthosis:
 - a. A thinner (and stronger) material is needed for the insert.
 - b. It would be preferable to be able to reshape the insert.
 - Eliminate the medial bar for light-duty applications to simplify fitting and joint placement.
 - d. Modify the cast to provide more support for the longitudinal arch and to prevent planovalgus and excess pressure along the medial border of the insert.
 - e. Use Loctite to prevent loosen-

ing of ankle joint screws.

9. Indications and Contraindications:

The only significant addition to those cited by the developer is that this orthosis is contraindicated where swelling in the foot exists.

10. Consensus:

It was the consensus that this orthosis is a valuable addition to patient service and that its most beneficial use is on patients with M-L instability and/or marked spasticity. The developer made note of minor improvements suggested by clinicians. Remarks made about the UC-BL shoe insert are also applicable to the insert portion of this orthosis.

Summary of Clinical Fittings of the UC-BL Dual-Axis Ankle Orthosis

1. Patients:

19 fittings on 18 patients (1 bilateral) 13 male, 5 female age range 15-71

2. Diagnosis:

peroneal nerve loss—7
hemiplegia or hemiparesis—6
incomplete paraplegia or
quadriplegia—3
polio—2

- 3. Patient Preference:
 - 14 preferred this orthosis (8 were previous wearers and 6 were not)
 - 4 did not prefer this orthosis
 (2 were previous wearers and
 2 were not)
- 4. Clinic Team Opinions:
 - 11 cases—the orthosis was satisfactory

- 4 cases—the orthosis was not satisfactory
- 3 cases—questionable
- 5. Main Advantages: freedom of movement lighter more cosmetic
- 6. Main Disadvantages:
 fabrication is difficult
 special alignment jigs are
 necessary
 insufficient dorsiflexion assist
 loosening of subtalar joint
 protrusion at heel

7. Remarks

- a. Of the 4 patients who did not prefer this orthosis,
 - 2 (1 peroneal nerve loss and 1 hemiparesis) with no previous orthoses rejected because of poor motivation
 - 1 (polio) preferred cosmesis of IRM spiral orthosis
 - (hemiplegia with splasticity) preferred conventional orthosis due to M-L instability
- b. Weight:

UC-BL orthosis — average 2 lb.

conventional orthosis — average 2½ lb.

- c. One UC-BL orthosis preferred by the patient had been modified to include double uprights for increased dorsiflexion assist.
- 8. Recommendations for Improvement of Orthosis:
 - a. Include frictional control of subtalar joint.
 - b. Consider use of stops at subtalar joint.

- Increase dorsiflexion assist by using double uprights or by rotating stirrup.
- d. Need stronger ankle assembly.
- 9. Indications and Contraindica-

This orthosis apparently can be fitted to dropfoot conditions of various origins. However, it appears contraindicated where there is M-L instability, sensory loss, or heavy-duty application.

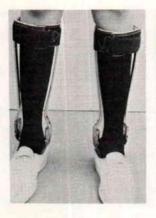
10. Other Experiences:

The UC-BL staff completed evaluation forms on 7 additional fittings. The results are similar to those described above.

- 5 preferred
- 2 did not prefer-
 - 1 due to M-L instability
 - 1 due to poor motivation

11. Consensus

Patients preferred the dual-axis ankle orthosis because of freedom of motion at the subtalar joint and because it is lighter and more cosmetic than the conventional ankle-foot orthosis. While it was difficult to assess the relative merit of the dual-axis feature itself, it was clear that patients very much like it providing they have sensation and sufficient eversion control of the subtalar joint. In particular, patients said they liked it when getting in or out of a car, going over uneven but not too rough ground, and in turning around. It was also evident that several patients did not use the subtalar joint motion when walking, e.g., patients with "old-





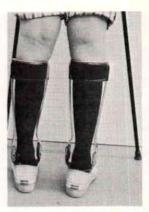








Fig. 6
Some Clinical Fittings of the NYU Insert Orthosis.

age" gait or with deformities and limited ranges of subtalar joint motion due to long-standing muscular imbalance of the inverters and everters.

The patients found the dualaxis orthosis very easy to don and doff. However, it was the strong feeling of all patients that they would like to have an orthosis which fits inside the shoe and is interchangeable with different shoes.

The dual-axis ankle orthosis seems ideally suited for patients who need dorsiflexion and eversion assistance and who have

M-L stability and sensation, assuming they have a range of subtalar joint motion to make good use of the orthosis. In practice, most of the long-term polio, peroneal-nerve injury and hemiplegic patients have deformities and limited ranges of subtalar joint motion and therefore are contraindicated. It is also contraindicated in cases of moderate to severe spasticity where the subtalar joint goes into uncontrollable inversion. Its prime use, therefore, seems to be on relatively new cases of peroneal nerve loss where there is the opportunity to allow and

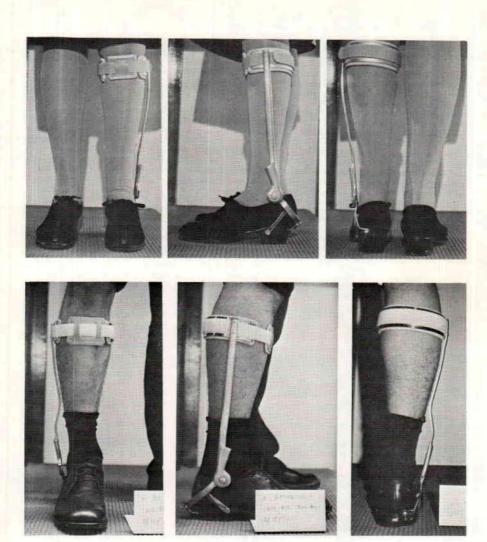


Fig. 7
Some Clinical Fittings of the UC-BL Dual-Axis Ankle Orthosis

maintain subtalar joint motion. Its application can also include patients with stabilized, mild spasticity and a therapeutic device for peroneal nerve injuries where there is a gradual return of function.

It was estimated by the clinics that 5-10 per cent of patients referred for ankle-foot orthoses could be fitted successfully with the dual-axis orthosis.

SUMMARY OF CLINICAL FITTINGS OF VAPC SINGLE-BAR ABOVE-KNEE ORTHOSIS

1. Patients:

16 fittings on 12 patients (4 bilateral)

8 male, 4 female













Fig. 8
Some Clinical Fittings of the VAPC Single-Bar Above-Knee Orthosis.

age range 12-55

- 2. Diagnosis:

 polio—6

 paraplegia or paresis—4

 osteoarthritis—1

 sciatic nerve loss—1
- 3. Patient Preference:
 - 4 preferred this orthosis (1 was a previous wearer and 3 were not)

- 8 did not prefer this orthosis (7 were previous wearers and 1 was not)
- 4. Clinic Team Opinions:
 - 4 cases—the orthosis was satisfactory
 - 8 cases—the orthosis was not satisfactory
- Main Advantages: useful for bilaterals more cosmetic

6. Main Disadvantages:

insecure feeling

heavy

lack of interchangeability of shoes

7. Remarks:

- a. Of the 8 patients who did not prefer this orthosis,
 - 5 felt unstable
 - 2 disliked the knee lock
 - 1 found it difficult to don and doff
- b. Weight

VAPC orthosis—average 5½ lb.

conventional orthoses—average 3½ lb. (aluminum); average 5¼ lb. (steel)

- c. On most fittings the free transverse rotation caused excessive internal rotation of the foot, and therefore this motion was eliminated in the orthosis.
- d. On most fittings the heavier (3/8" diameter) rod was needed.
- Kneecaps were used on several fittings.
- 8. Recommendations for Improvement of Orthosis:
 - a. Eliminate transverse rotation and spring.
 - b. Place transverse rotation at level of subtalar joint.
 - c. Extend the tibial flare more proximal for increased M-L stability and make cuff of plastic for better contour.
 - d. Modify orthosis to increase stability.
 - e. Improve methods of measurement and fabrication.

- f. Cast whole leg and fabricate orthosis over cast.
- g Provide stronger, lighter material for upright.
- Indications and Contraindications:

Those proposed by developer appear to be satisfactory, though clarification is needed in certain cases.

10. Other Experiences:

This orthosis is also being fitted for evaluation at several VA orthopedic brace facilities. Results are not yet available.

11. Consensus:

Most of the patients who did not prefer this single-bar orthosis were previous wearers of a conventional, double-upright, kneeankle orthosis. Most of the criticism of the new orthosis was that the patients felt "insecure" or "unstable." Upon closer examination patients seemed to feel either that the knee was going to buckle or that there was inadequate M-L stability. These remarks seemed to stem from the shape and location of the calf and thigh shells and from the "springiness of the one upright.

As with the UC-BL orthosis, it was the strong feeling of all patients that they would like to have the orthosis fit inside the shoe and be interchangeable with different shoes. Also, several patients objected to the difficulty of changing clothes with the VAPC single-bar orthoses because it is not readily detachable from the stirrup and shoe.

The VAPC orthosis seems best

intended for "light duty" use to hold the lower limb in proper alignment for supporting weight without the need to provide large corrective forces. Except for its weight, the orthosis also seems well indicated for bilateral use since it eliminates both of the medial uprights. It appears contraindicated where there is more than slight varus or valgus of the knee, knee-flexion contracture, severe spasticity, or "heavy duty" use because the single-bar and calf-and-thigh shell construction is not strong enough for these applications.

It is not clear from the developer's prescription criteria or from the 16 clinical trial fittings just what the hip musculature should be to use the orthosis effectively. However, it is clear that at least some hip-flexor power is required. In general, the orthosis was more difficult to fit and align than a conventional double-upright type, but, once fitted, it was easier to make adjustments because only one upright is involved. Also, with only one upright, anklejoint placement is simplified and it can be placed obliquely to closer simulate anatomical ankle motion. All of the clinics liked the idea of using just one side bar, but all said they would not use this orthosis without making major design changes.

RECOMMENDATIONS

UC-BL SHOE INSERT

The UC-BL shoe insert orthosis should be included in the educa-

tional program. The manual appears to be satisfactory, though it is possible to use a few alternate techniques in fabrication. The biomechanical and fitting principles must be learned well for success to be achieved with the shoe insert.

NYU INSERT ORTHOSIS

The NYU insert orthosis should be included in the educational program with the observation that it is particularly worthwhile for patients with M-L instability and/or marked spasticity. The manual appears to be satisfactory, though minor changes in the stirrup hardware need to be made.

UC-BL DUAL-AXIS ANKLE ORTHOSIS

On selected patients, the dual-axis ankle motion afforded by this orthosis is a definite benefit to and is desired by those patients.

The principle of the dual-axis motion and the associated biomechanics of the foot and ankle are very important and should be included in the curricula of the prosthetic and orthotic schools.

Because of the relative time and complexity in fabricating this orthosis and because of the minority of patients for whom it appears indicated, it is doubtful whether it would find wide acceptance by the orthotic field.

There is promise that a simpler, lighter, more cosmetic, plastic, shoe-insert type of ankle-foot orthoses can be designed to incorporate the dual-axis motion. If this can be done, the benefits to the pattient would be improved materially.

This orthosis has established a sound principle for providing an

analogue motion of the ankle and subtalar joints, and is regarded as a prototype to be considered in future designs of all joints.

It is recommended that further development and/or production of the UC-BL dual-axis ankle orthosis be held in abeyance while effort is undertaken immediately to find a more optimal way of providing the dual-axis motion using the principles developed by UC-BL.

VAPC SINGLE-BAR ABOVE-KNEE ORTHOSIS

The concept of using a single bar is a worthy one and should be further explored, but a major redesign seems to be required before the present design is apt to be accepted widely.

It is suggested that future design and development efforts consider the following points:

a. The Nitschke single-bar above-knee orthosis has worthwhile features which might be utilized in the VAPC orthosis; namely, the shoe insert, the strap posterior to knee which tightens when standing and loosens when sitting, the Polysar pretibial cuff, and the Silesian belt for hip control and unweighting.

b. The calf shell might be made as a pretibial or half shell. The thigh shell might be made in quadrilateral shape with posterior openings as allowed by patient circumstances.

c. The calf and thigh shells might be made of plastic formed over a model from a cast of the leg, thus utilizing plastic instead of leather and obviating the shaping of the metal bands on the patient.

d. The stirrup might be attached to a shoe insert made of plastic,

giving the advantages of stabilizing the foot inside the shoe and a more cosmetic appearance, and allowing interchangeability of shoes.

SUMMARY OF THE FINDINGS

Results of the evaluation indicated that the UC-BL shoe insert and the NYU insert orthosis are worthwhile devices, are ready for clinical use, and are recommended for inclusion in educational programs. The UC-BL dual-axis ankle orthosis was accepted in principle as providing a beneficial function and as a forerunner in allowing anatomical motion; however, it is recommended that its practical application be held in abevance while efforts to accomplish the same purpose more effectively are completed. The VAPC single-bar above-knee orthosis has some worthy features, but it is the consensus of the subcommittee that a major redesign is required to meet clinical requirements.

Literature Cited

1. Campbell, J. W., W. H. Henderson, and D. E. Patrick, UC-BL dual-axis ankle-control system: Casting, alignment, fabrication, and fitting, Bull. Pros. Res., BPR 10-11, 184-235, Spring 1969.

2. Committee on Prosthetics Research and Development, Report of Seventh Workshop Panel on Lower-Extremity Orthotics of the Subcommittee on Design and Development, National Academy of Sciences, March 1970.

3. Henderson, W. H., and J. W. Campbell, *UC-BL* shoe insert: Casting and Fabrication, Bull. Pros. Res., BPR 10-11, 215-235, Spring 1969.

4. Inman, V. T., UC-BL dual-axis ankle-control system and UC-BL shoe insert: Biomechanical considerations, Bull. Pros. Res., BPR 10-11, 130-145, Spring 1969.

5. Lamoreux, Larry W., UC-BL dual-axis ankle-control system: Engineering design, Bull. Pros. Res., BPR 10-11, 146-183, Spring 1969.

6. New York University insert orthosis fabrication manual (draft), undated.

7. VAPC Draft Manual, Single-bar leg and leg-thigh braces, Sept. 15, 1970.

APPENDIX A

Procedure for Clinical Evaluation of NYU Insert Orthosis UC-BL Dual-Axis Ankle Orthosis, UC-BL Shoe Orthosis and VAPC Single-Bar Above-Knee Orthosis

Background

The clinical evaluation of the above four leg braces is part of an overall evaluation program being sponsored by SRS and coordinated by CPRD. The purpose is to help provide an effective transition from design and development to patient usage. Other new orthotic and prosthetic devices and techniques will be clinically evaluated as they become available and as funding and manpower permit.

General Method of Evaluation

Orientation sessions are being held for the developers of the new items to transfer their knowledge and experience to other clinics so they in turn can go home and fit patients for independent evaluation. The results of the fittings at the various clinics will furnish the basis for recommendations for patient usage. Underlying this method of evaluation, certain procedures must be followed to make the evaluation effective and worthwhile. All clinics must be taught the same way; all clinics must make the items as taught; and there must be a common protocol for all the clinics to obtain and report their findings.

Protocol

The same protocol will be used for all the braces. Patients who need the respective braces will be chosen as subjects, whether or not they have conventional or other braces already. Each patient will be used only once, i.e., only for the evaluation of one brace. Following satisfactory fabrication, fitting, and training, the patient will wear the brace for one month. Forms to be completed before and after the trial wear period will provide the basis for reporting results. Site visits will be made by the CPRD staff to see how the evaluation is going and if assistance can be given, such as calling in the developer for technical help, getting patients from other clinics, getting parts, etc.

Explanation of Forms

Below are listed the forms to be completed for each brace fitted. Emphasis has been placed on getting good, subjective information by responsible people rather than having detailed and time-consuming data forms. CPRD feels it is important, however, that the whole clinic team at each facility participate in the evaluation. Certainly, the physician must be involved with the selection of the patient regarding analysis of disability and prescription of brace. Likewise, the therapist in most facilities will be involved with training and patient follow-up.

Form 1: SELECTION OF PA-TIENT FOR TRIAL WEAR OF NEW BRACE

This form is for recording in-

formation about the patient and his impairment in choosing him as a subject.

Form 2: PATIENT'S OPINIONS
AND CLINIC TEAM'S
EVALUATION OF CONVENTIONAL OR PRESENT
BRACE—IF ANY

This form is for getting information about the patient's present brace and gait for later comparison with the new brace.

Form 3: PATIENT'S REAC-TIONS AND CLINIC TEAM'S EVALUATION OF NEW BRACE

This form is for getting information about the new brace, without comparison, the same way as was done on Form 2 for the patient's previous brace.

Form 4: CONCLUSIONS BY PATIENT AND CLINIC TEAM

This form is for recording the

patient's comparative judgment and the clinic team's recommendations on the use of the new brace. Forms 2 and 3 provide a check to verify if what the patient says agrees with how well he did with the new brace.

Final Report and Recommendations

When the fittings at the clinics are completed and the evaluation forms are returned to CPRD, a tabulation of the results will be prepared. A meeting of the Subcommittee on Evaluation will be held, with the clinics and developers present, to consider the results and to recommend future courses of action. A final report will then be written. For the meeting and final report, it would be helpful if the clinics would submit black-and-white photographs of each patient fitted with the new brace, with his previous brace, and with no brace.

SELECTION OF PATIENT FOR TRIAL WEAR OF NEW BRACE

| Name | Occupation | Age | Sex |
|---|------------|-------|------|
| Address | | Phone | |
| Analysis of impairment: | | | |
| | | | |
| | | | |
| Type of brace for which | | | |
| Does patient conform to Does patient have any ot | | | |
| the brace? (If so, please | explain.) | | |
| | | | |
| | | | |
| Sig | nature | | Date |

PATIENT'S OPINIONS AND CLINIC TEAM'S EVALUATION OF CONVENTIONAL OR PRESENT BRACE—IF ANY

(to be completed prior to fitting of new brace)

PATIENT'S OPINIONS

| Name of patient | | | | | | |
|---|---|---|--|--|--|--|
| Type of present brace | | | | | | |
| Main advantage of present brace: | | | | | | |
| Main disadvantage of present brace: | | | | | | |
| Comfort (standing and s
Function (walking):
Weight:
Strength:
Appearance:
What like most about pre | Works well ☐ Heavy ☐ Strong enough ☐ Cosmetic ☐ | Does not fit well Does not work well Light Not strong enough Not cosmetic | | | | |
| What dislike most about | present brace: | | | | | |
| CLINIC TEAM'S EVAL Brief description of prese | | | | | | |
| Weight of brace with she
Gait analysis with presen | | | | | | |
| Gait analysis without bra | nce: | | | | | |
| Sig | gnature | Date | | | | |

PATIENT'S REACTIONS AND CLINIC TEAM'S EVALUATION OF NEW BRACE

(to be completed after one month's wear)

PATIENT'S REACTIONS Name of patient Type of new brace Hours/day wear Main advantages of new brace: Main disadvantages of new brace: Comfort (standing and sitting): Fits well Does not fit well Works well Does not work well Function (walking): Weight: Heavy [Light [Not strong enough [Strength: Strong enough Cosmetic Not cosmetic \ Appearance: What like most about new brace: What dislike most about new brace: CLINIC TEAM'S EVALUATION Weight of new brace with shoe: Gait analysis with new brace: Other comments:

Signature

Date

CONCLUSIONS BY PATIENT AND CLINIC TEAM

| PATIENT'S CONCLUSIONS | |
|--|---|
| Does patient prefer present or new brace | e? |
| If patient has no previous brace, does he | want to keep the new brace? |
| If patient has a previous brace, is the ne | ew brace: |
| More comfortable | Less comfortable |
| More functional | Less functional |
| Lighter | Heavier |
| Stronger | Less strong □ |
| More cosmetic | Less cosmetic |
| CLINIC TEAM'S CONCLUSIONS | |
| Was the patient's gait improved with th | e new brace? |
| Would you prescribe the new brace for | |
| | |
| | |
| Would you prescribe the new brace for | other patients? |
| | |
| Were fabrication, fitting, and training pr | rocedures satisfactory? (If not, please |
| explain.) | |
| | |
| Was repair necessary? | |
| Are the indications and contradictions s | atisfactory? |
| | |
| Orthotist's suggestions for improvement | t of the new brace: |
| | *************************************** |
| | |
| | |
| | |
| Signature | Date |

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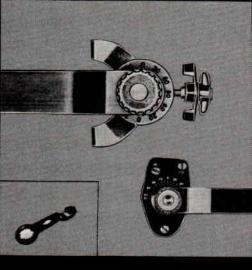
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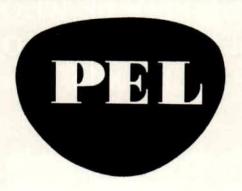
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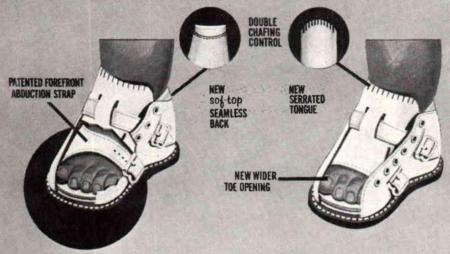
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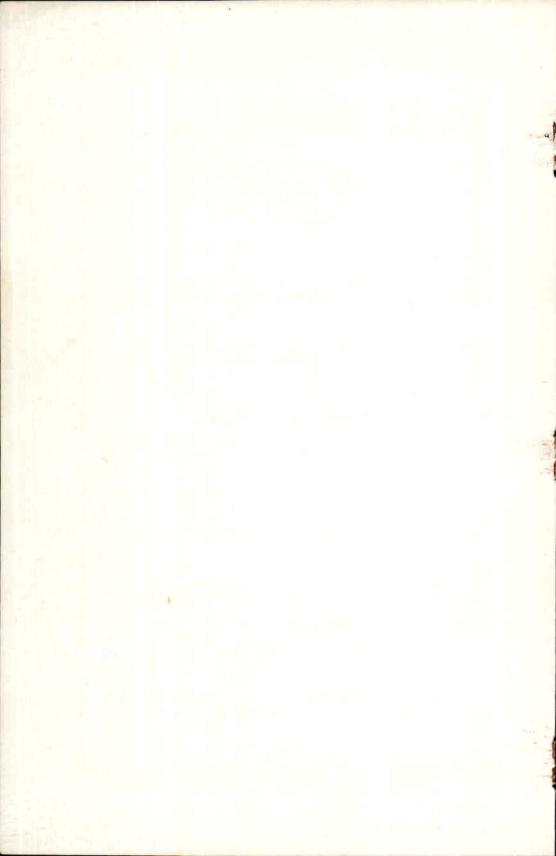
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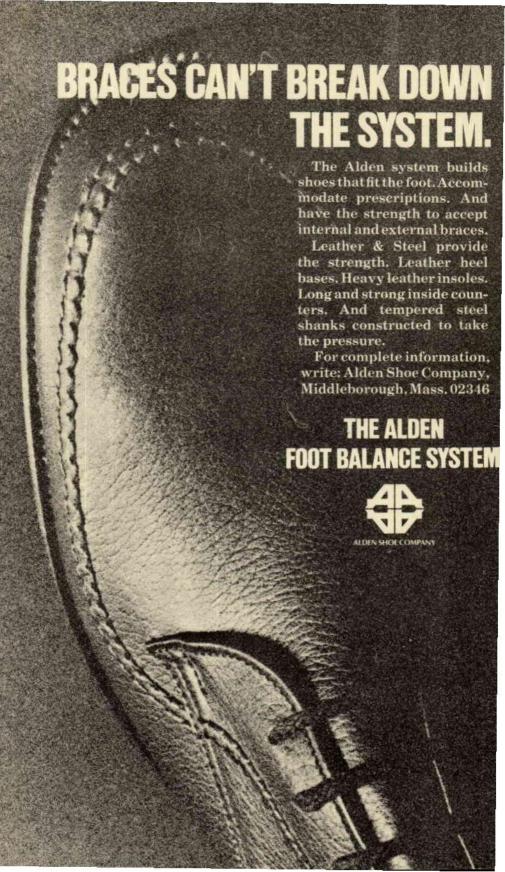
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