

# 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.

\* 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.

\*\* 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



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.

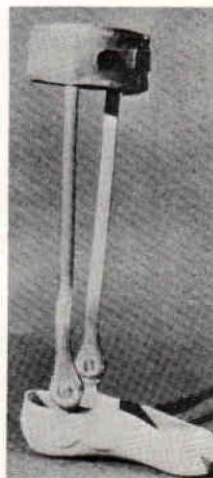


Fig. 2  
NYU Insert Orthosis.



### *Description*

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

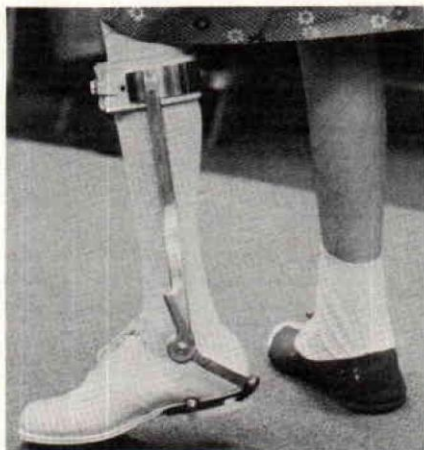


Fig. 3  
UC-BL Dual-Axis Ankle Orthosis.

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 rubber-band 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 above-knee brace except that the thigh and calf cuffs are shaped and fitted so as to provide appropriate reaction forces on the medial side normally



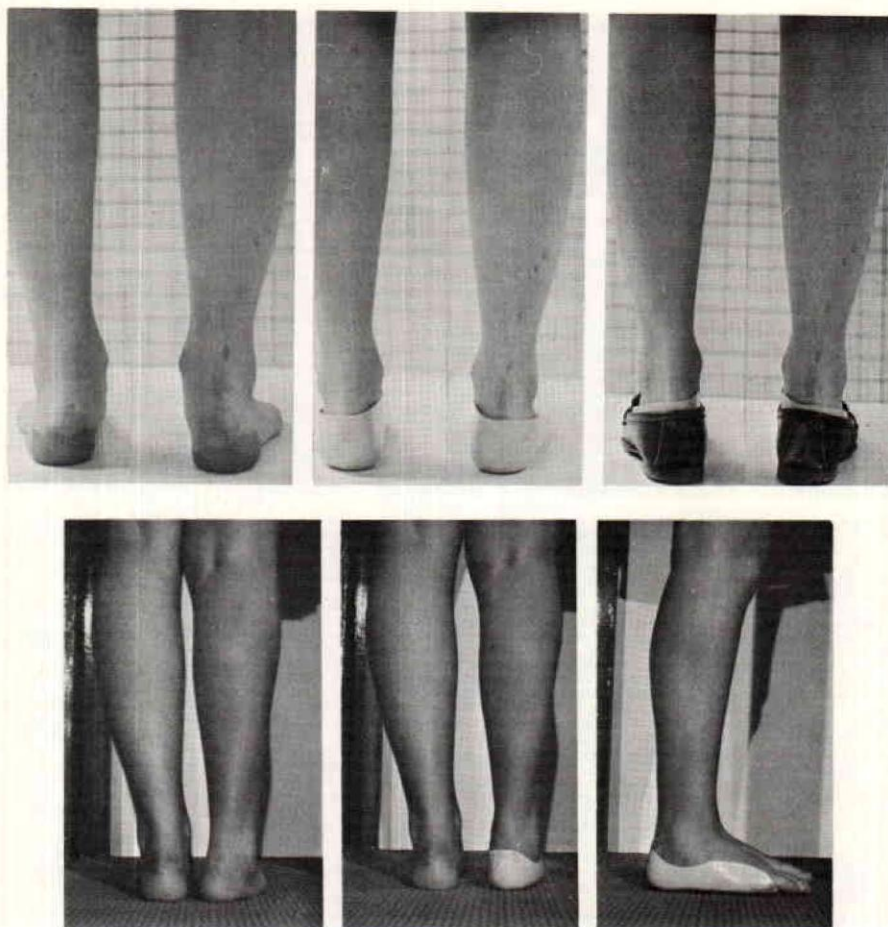


Fig. 5

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
plantar fasciitis	4
polio	3
metatarsal pain	2
arthritis	1
weak arches	1
subtalar joint pain	1
hemiplegia	1
talipes cavus	1
talipes varus	1
incomplete quadriplegia	1
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
4. 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



5. Main Advantages: relief of pain; proper support of foot

6. Main Disadvantages: requires wider shoe in some cases; difficult to fit well; some became loose-fitting with wear

7. Remarks:

a. Of the 3 patients who did not prefer this orthosis

1 (arthritis) rejected because of severe swelling

1 (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.

c. 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.

9. 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

6. 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 2¼ 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.
- c. 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 loosening 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
    - 1 (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.

- c. Increase dorsiflexion assist by using double uprights or by rotating stirrup.

- d. Need stronger ankle assembly.

#### 9. Indications and Contraindications:

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-

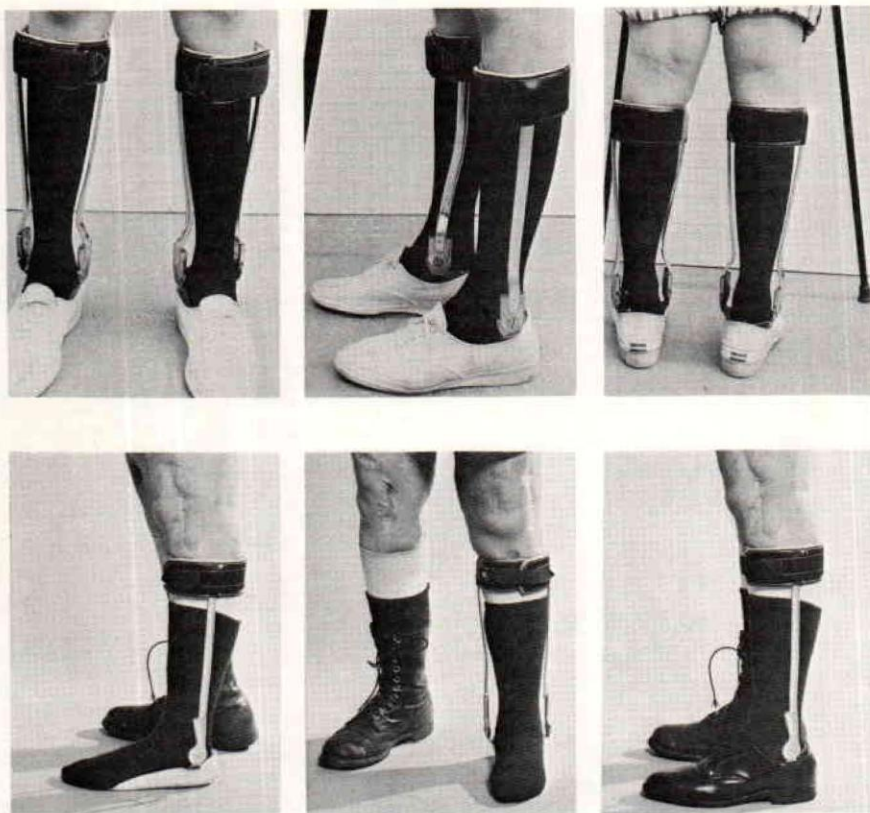


Fig. 6  
Some Clinical Fittings of the NYU Insert Orthosis.

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 dual-axis 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



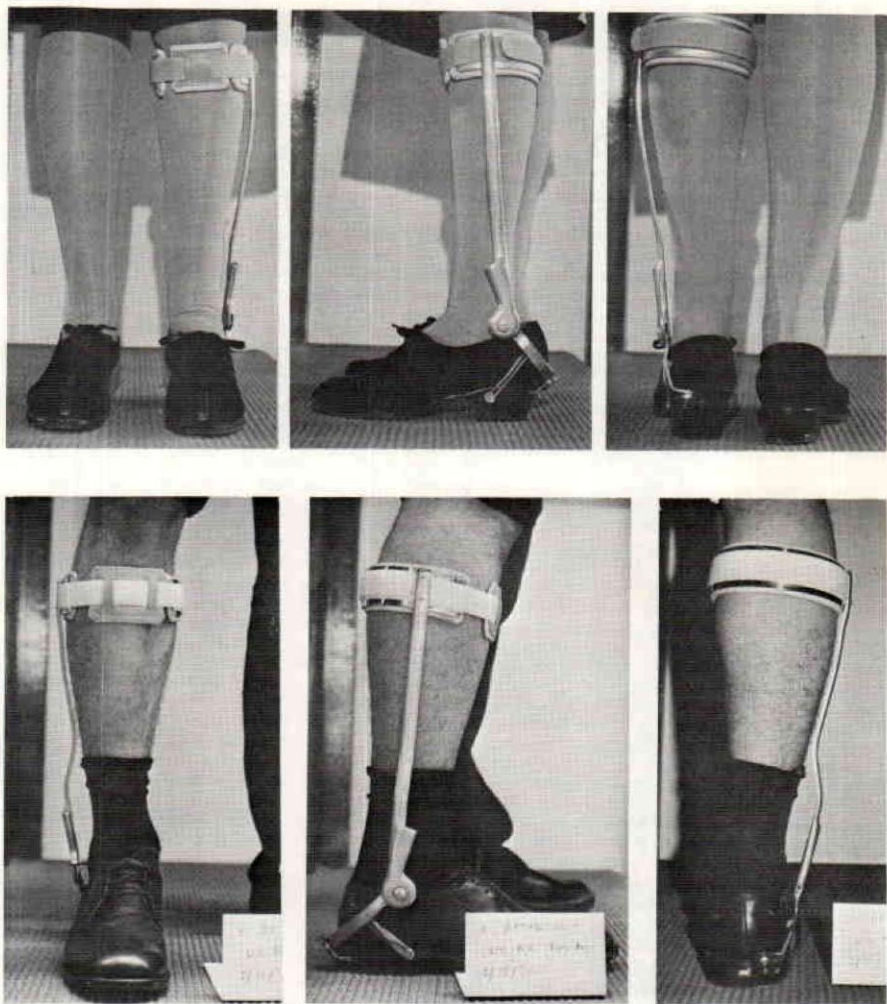


Fig. 7

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

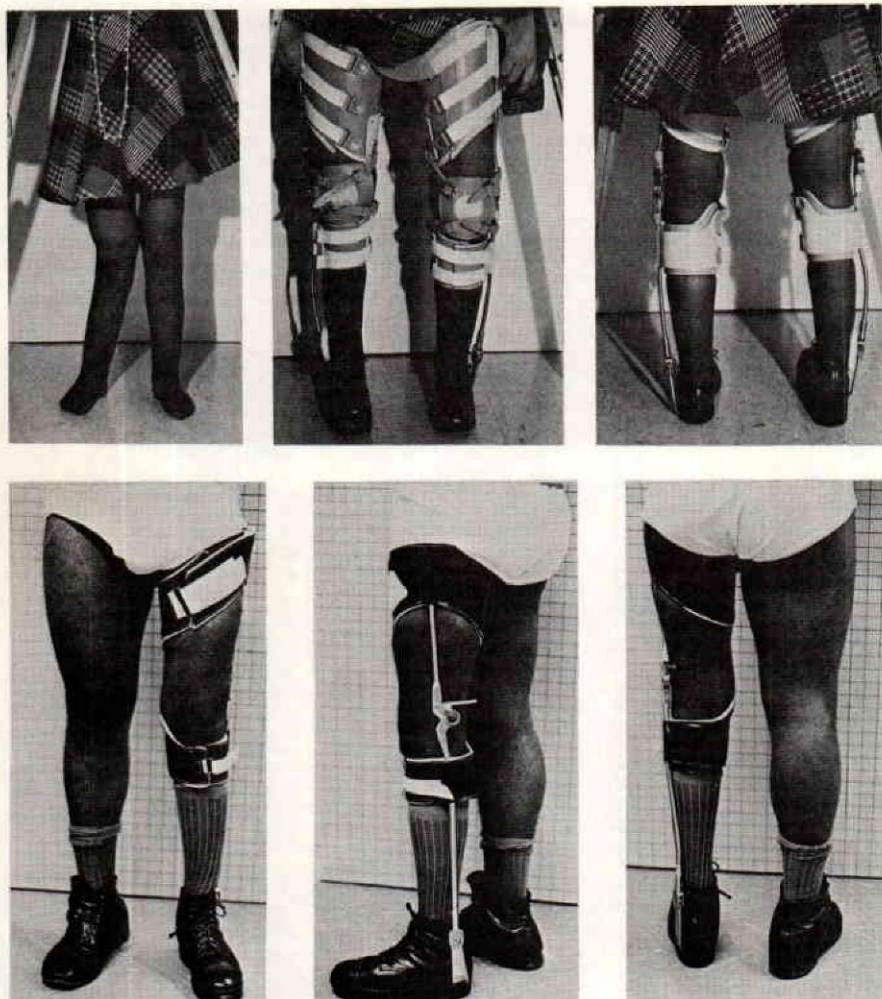


Fig. 8

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
  5. 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 (¾" diameter) rod was needed.

e. 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.

9. 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, knee-ankle 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, ankle-joint 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 patient 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 abeyance 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 REACTIONS 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.

**Form 1**

**SELECTION OF PATIENT FOR  
TRIAL WEAR OF NEW BRACE**

Name ..... Occupation ..... Age ..... Sex .....

Address ..... Phone .....

Analysis of impairment: .....

.....  
.....  
.....

Type of brace for which patient is being considered: .....

Does patient conform to prescription criteria for new brace? .....

Does patient have any other problems which would affect the evaluation of  
the brace? (If so, please explain.) .....

.....  
.....

.....  
Signature

.....  
Date



## Form 2

### 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 ..... Hours/day wear .....

Main advantage of present brace: .....

Main disadvantage of present brace: .....

Comfort (standing and sitting): Fits well ☐ Does not fit well ☐

Function (walking): Works well ☐ Does not work well ☐

Weight: Heavy ☐ Light ☐

Strength: Strong enough ☐ Not strong enough ☐

Appearance: Cosmetic ☐ Not cosmetic ☐

What like most about present brace: .....

What dislike most about present brace: .....

#### CLINIC TEAM'S EVALUATION

Brief description of present brace: .....

Weight of brace with shoe: .....

Gait analysis with present brace: .....

Gait analysis without brace: .....

Signature

Date

Form 3

**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 <input type="checkbox"/>	Does not fit well <input type="checkbox"/>
Function (walking):	Works well <input type="checkbox"/>	Does not work well <input type="checkbox"/>
Weight:	Heavy <input type="checkbox"/>	Light <input type="checkbox"/>
Strength:	Strong enough <input type="checkbox"/>	Not strong enough <input type="checkbox"/>
Appearance:	Cosmetic <input type="checkbox"/>	Not cosmetic <input type="checkbox"/>

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



**Form 4**

**CONCLUSIONS BY PATIENT AND CLINIC TEAM**

***PATIENT'S CONCLUSIONS***

Does patient prefer present or new brace? .....

If patient has no previous brace, does he want to keep the new brace?.....

If patient has a previous brace, is the new 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 the new brace? .....

Would you prescribe the new brace for this patient? (If not, please explain.)

.....  
.....

Would you prescribe the new brace for other patients? .....

.....

Were fabrication, fitting, and training procedures satisfactory? (If not, please explain.) .....

.....

Was repair necessary? .....

Are the indications and contradictions satisfactory? .....

.....

Orthotist's suggestions for improvement of the new brace: .....

.....

.....

Signature

Date