Evaluation of the Ortho-Walk Type B Pneumatic Orthosis on Thirty-Seven Paraplegic Patients (1976)

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EVALUATION OF THE ORTHO-WALK TYPE B

PNEUMATIC ORTHOSIS ON THIRTY-SEVEN PARAPLEGIC PATIENTS

COMMITTEE ON PROSTHETICS RESEARCH AND DEVELOPMENT
COMMITTEE ON PROSTHETIC-ORTHOTIC EDUCATION
ASSEMBLY OF LIFE SCIENCES-DIVISION OF MEDICAL SCIENCES
NATIONAL RESEARCH COUNCIL

NATIONAL ACADEMY OF SCIENCES
Washington, D.C.
1976

NOTICE

The project that is the subject of this report was approved by the Governing Board of the National Research Council, whose members are drawn from the Councils of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine. The members of the Committee responsible for the report were chosen for their special competences and with regard for appropriate balance.

This report has been reviewed by a group other than the authors according to procedures approved by a Report Review Committee consisting of members of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine.

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PREFACE

The evaluation of the Ortho-Walk Pneumatic Orthosis was requested by the Veterans Administration (VA) and the Rehabilitation Services Administration (RSA), Department of Health, Education, and Welfare. The Veterans Administration originally became interested in pneumatic orthoses after contacts with the French developers of the Ortazur Orthosis, the forerunner of the Ortho-Walk.

Dr. George Morel of Berck Plage, France, introduced the Ortazur Pneumatic Orthosis in 1965. Although the orthosis was originally used quite successfully on children with osteogenesis imperfecta, Dr. Morel later used it on a three-year-old child with traumatic paraplegia. The orthosis was later used with positive results by a number of French physicians to stand patients with Duchenne Dystrophy, cerebral palsy, and paraplegia. In most cases, the primary goal of these physicians was to support the knee and hip joints in order to bring the patient to an erect position, with a secondary goal of ambulation.

In March 1973, the vice president of the Aerazur Company, which manufactures the Ortazur in France, and four other staff members visited the Castle Point VA Hospital in New York and fitted three patients with the pneumatic orthosis. A fourth orthosis was subsequently fitted to another patient at this hospital, and all patients were asked to provide feedback to the Veterans Administration Prosthetics Center concerning the utility of the orthoses. This informal evaluation demonstrated that the high paraplegic may be able to use the orthosis for standing, although ambulation was impractical.

A study of both the Ortho-Walk and the Ortazur pneumatic orthoses on 11 patients at Bird S. Coler Hospital, New York, by

Maurycy Silber, M.D. (14), identified several positive physiological outcomes from regular use of the pneumatic orthoses, and underscored the need for a large scale, formal evaluation of the Ortho-Walk pneumatic orthosis on paraplegic people.

The ILC Dover Company* obtained an exclusive license to manufacture and distribute the pneumatic orthosis in the United States and first introduced a modified version of the Ortazur Pneumatic Orthosis, called the Ortho-Walk, in October 1973 at a combined meeting of the American Congress of Rehabilitation Medicine and the American Academy of Physical Medicine and Rehabilitation in Washington, D.C. ILC Dover is the Division of ILC Industries, Inc. that was the sole designer and manufacturer of the space suits for Project Apollo and Skylab.

National interest in this new orthosis was high, not only because of the large amount of publicity it was given, but also because the Type B Ortho-Walk Pneumatic Orthosis appeared to be of real benefit to people with paraplegia, since it stabilizes the knee, hip, lower spine, and to some extent, the ankle.

The Veterans Administration recognized the possible benefits for the 20,000 paraplegic and quadriplegic patients under its care and requested the Committee on Prosthetics Research and Development (CPRD), National Research Council, to conduct a large structured evaluation of the Ortho-Walk Type B Pneumatic Orthosis on people with paraplegia in both VA and non-VA hospitals.

MICHAEL J. QUIGLEY, C.P.O.
Committee on Prosthetics Research
and Development

*ILC Dover Company, 350 Pear Street, Dover, Delaware 19901.

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The Committee on Prosthetics Research and Development wishes to thank Maurycy Silber, M.D., and his staff at Bird S. Coler Hospital for providing the training for evaluation participants; G. Heiner Sell, M.D., and his staff at the Institute for Rehabilitation Medicine, for lending their expertise to steer the evaluation along with Dr. Silber. Harry Hahn, M.D., and his staff at Craig Rehabilitation Hospital also receive our thanks for hosting the final meeting of the evaluation. The evaluation could not have been conducted without a great amount of effort, which was contributed by seven physicians, seven orthotists, and eight therapists, to whom the Committee is most grateful.

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POPULATION OF PEOPLE WITH PARAPLEGIA

The National Center for Health Statistics (NCHS) report "Prevalence of Selected Impairments - 1971" states that in the civilian noninstitutionalized population there are approximately 1.4 million people with paralysis, complete or partial. Of this number, about 102,000 people have paraplegia, or 0.5 people per 1,000 persons. Since many paraplegics are institutionalized, the estimate is probably low. Assuming that about 10 percent of the paraplegic population was institutionalized or in a noncivilian status at the time of the 1971 survey, there would be about 112,000 persons with paraplegia in this country at that time. In 1975, there are probably from 120,000 to 140,000 persons with paraplegia in the United States.

According to Peter C. Hofstra, M.D. (4), Chief of the VA Spinal Cord Injury Services, the population of spinal-cord-injured people is increasing by 10,000 to 20,000 persons per year. The highest incidence of spinal-cord injury occurs in young males between the ages of 15 and 35 years. Approximately 50 percent are paraplegics and 50 percent are quadriplegics.

PRESENT USE OF ORTHOSES FOR PERSONS WITH PARAPLEGIA

The history of the orthotic treatment of paraplegia does not go back much further than World War II, since previous to that time about 90 percent of the spinal-cord-injured persons died from genitourinary infections. The development of antibiotics to combat these infections reversed the fatality rate shortly after World War II (4).

The physiological benefits of standing persons with paraplegia were first mentioned by Abramson (1) in 1948, who stated that an hour of standing each day will prevent osteoporosis in the lower limbs and helps to prevent urinary calculi and genitourinary infections. In 1964, Rusk (12), stated that "circulation and nutrition, as well as morale, are also aided by keeping the patient in the upright position for several hours each day."

Rusk also recommended that the tenth thoracic vertebra be used as a landmark when prescribing orthoses; lesions at or superior to this level are usually given double-bar long-leg braces with a pelvic band and Knight spinal attachment (current terminology is LSHKAFO, or lumbo-sacral-hip-knee-ankle foot orthosis); lesions inferior to this level are prescribed the same orthoses without the spinal attachment, and lesions inferior to L_1, are fitted without the pelvic band.

Hahn (3), Scott (13), Edberg (2), and Warren *et al.*, (15), do not advocate the use of the pelvic band on paraplegic patients. Edberg feels that the pelvic band must apply excessive pressure against the skin to be effective, that it causes difficulty in donning the orthosis, limits flexibility and adds excessive weight. Hahn and Scott state that the two most important considerations for orthotic design for paraplegics are ease of donning and control of ankle dorsiflexion, hence the so-called Craig-Scott design KAFO has no pelvic band, only one thigh band, and a fixed but adjustable ankle joint.

Another method of providing standing mobility to paraplegic people is by using standing frames. Motloch (7) has demonstrated success with the "parapodium," a jointed standing frame for spinal-cord-impaired children. Prast (9) is working on an adult version of Motloch's parapodium, which will provide standing stability and allow "pivot walking," which is a combination of rotating and sliding the base of the device in the desired direction. A "mobile, portable, collapsible set of standing bars" is the way Peizer and Bernstock (8) described another device, called the "Stand-Alone."* In an evaluation of the device on 32 patients, the Stand-Alone proved to provide "hand free" independent standing and mobility on level and slightly sloped surfaces for most paraplegics up to the level of T_8, providing the person could tolerate the standing position.

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*Stand Alone, Corporation for Medical Engineering, 8472 East Garvey Ave. San Gabriel, California 91771.

Despite the various orthotic designs available, and the philosophies that accompany each design, the majority of paraplegic persons will either reject their orthoses or not have them prescribed. There are many reasons for this, the main one being the excessive energy expenditure needed to ambulate in an orthosis. The donning procedure for most orthoses is difficult and time consuming, and once the orthoses are on the patient they often interfere with transfer activities. In addition, crutches are needed for stability while standing and ambulating, which limits the use of the hands and arms. Other problems with standing ambulation for paraplegic patients are the lack of bladder control while standing and the obviously abnormal walking pattern.

Hussey and Stauffer (5) studied the ambulatory function of 164 spinal-cord-injured patients and stated that "no patient achieved any form of functional ambulation without pelvic control* and there appeared to be no effective method of bracing patients to overcome this deficit." The nerve supply for the pelvic control muscles is affected by a thoracic lesion.

Rosman and Spira (11) reported similar problems in ambulating patients with thoracic lesions. In a study of 35 patients with lesions from the T_1, to T_{11} level who were fitted with orthoses for ambulation, only one patient was ambulating out of the hospital, and five used the orthosis for standing only. The report concluded "that there is an essential difference between the 'occupation' of walking in the non-pressured rehabilitation environment and walking when faced with the problems of everyday life." It further concludes that "some disabled persons with unusual strength, willpower, and motivation for walking will successfully overcome the difficulty, effort, and social strain involved in the continuous use of braces," but that "most will eventually relinquish these goals because the effort proves too great."

*The Term "pelvic control" used here refers to the ability of the abdominals to move the pelvis when body weight is on the crutches.

Initial studies on pneumatic orthoses showed promise, especially for patients with thoracic lesions. Silber (14) reported on 11 patients, nine of them with lesions at T_{12} or superior, in 1975. All patients in the study were inpatients. He stated that all patients could transfer independently, all but one patient could don the orthosis independently, and all could stand and ambulate, although not always independently. Of the six patients who also received conventional metal orthoses, five could not don the orthosis independently. However, after about two weeks training with the pneumatic orthosis, all of them could don it without help. All patients felt that the pneumatic orthosis was more comfortable than the conventional orthosis, and found that it made activities-of-daily-living (ADL) functions much easier. Silber used both the Type A Pneumatic Orthosis which stabilized the knee only, and the Type B, which stabilizes the trunk, hip, and knee in his study. He also used both the French Ortazur style and its American counterpart, the Ortho-Walk.

Ragnarsson *et al.*, (10), at the Institute of Rehabilitation Medicine, New York University Medical Center, studied 14 patients using the Ortho-Walk and the French Ortazur pneumatic orthoses. Eleven of these patients were also fitted with conventional metal orthoses. Energy consumption of three patients may have been less with pneumatic orthoses than with conventional orthoses, although it is not clear that the devices were evaluated on comparable tasks. Patients could, however, ambulate further and for a longer time in the pneumatic orthosis. However, only one of ten patients preferred the pneumatic orthosis over the conventional orthosis because of inadequate support at the knees and hips, zipper failures, and most of all, inflation problems. The study concludes that for many reasons the pneumatic orthosis is especially suitable for early ambulation training, but severe mechanical problems limit its usefulness for community ambulation.

In summary, many designs of orthoses are presently prescribed for paraplegic adults but in nearly every case, when a thoracic level lesion is present, the orthoses prove to be impractical and are rejected. Wheeled

standing frames are being used successfully on children, and are beginning to gain acceptance with adults. Initial results with pneumatic orthoses were promising, and therefore an evaluation of this orthosis has been conducted.

DESCRIPTION AND FITTING OF THE PNEUMATIC ORTHOSIS

The Ortho-Walk Type B Pneumatic Orthosis (Fig. 1) is available in six standard sizes. Each orthosis has three pneumatic beams on the anterior and posterior aspect of each leg. A model with four pneumatic beams on the anterior and posterior aspect of each leg is also available and is recommended for people weighing over 160 pounds. The garment is made of nylon, and the pressure bladders in the pneumatic beams are polyurethane. The orthosis incorporates values for inflation and deflation, a series of straps and laces for fitting and adjustment, zippers for donning and doffing, and toe lifter straps, which attach to the shoes.

The size of the orthosis needed for a particular patient is determined by relating ten measurements of the patient to a sizing chart, and then choosing the size that most nearly corresponds to the measurements. Custom orthoses are available for people who do not fit into the standard-size range due to obesity, excessive height, etc. The manufacturer recommends that long cotton underwear be worn under the orthosis. Regular clothes may be worn over the orthosis.

Two types of air compressors are available, an AC compressor and a DC compressor. The AC compressor is used as a stationary item, generally used in the household. The DC compressor is termed "portable," and comes with a carrying case, battery and charger, and may also be operated from an automobile cigarette lighter. Other types of inflation techniques, such as small compressed gas cartridges and pumps, have proved to be impractical, although larger cylinders similar to scuba tanks, may be used.

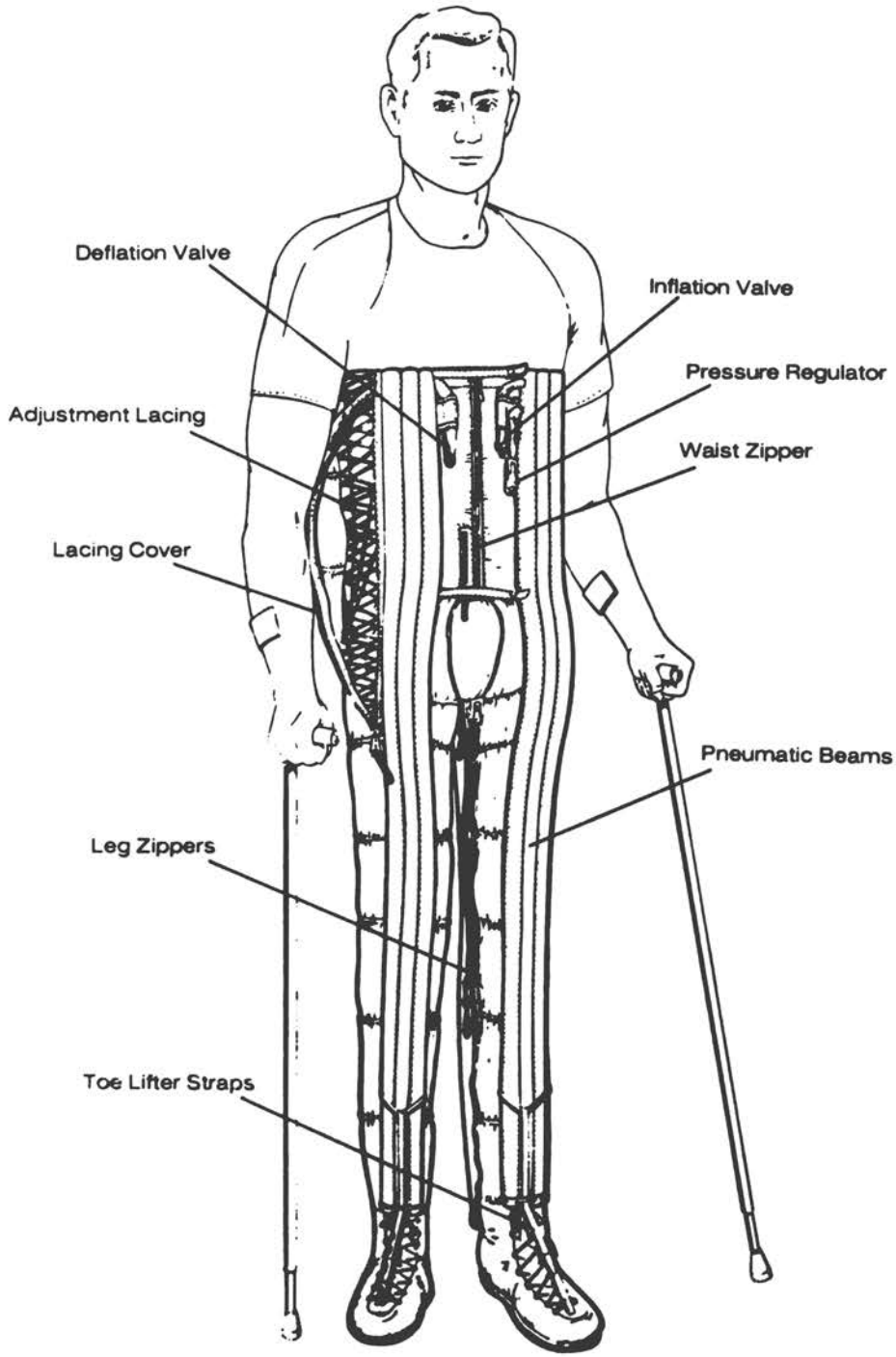

Fig. 1. Ortho-Walk Type B Pneumatic Orthosis. The pneumatic beams on the anterior and posterior aspect of each leg support the knees, hips, and trunk.

Fitting of the orthosis is generally done by an orthotist, preferrably on a waist-high bed or tilt table. The zippers covering the adjustment laces and straps are opened and the orthosis is spread out on the table. The patient (wearing shoes and long underwear) is then positioned supine on the orthosis and the heel straps are secured around his shoes. The position of the patient on the orthosis is then checked, as is the length of the orthosis. The posterior pneumatic beams are aligned in a straight line; then long and short zippers are closed.

The orthosis is inflated to straighten the pneumatic beams and the laces and straps are adjusted to maintain this alignment (Fig. 2). The zippers covering the adjustment straps and laces are then closed and the toe lifter strap is fastened to the shoe and tightened until the ankle is held at approximately 90 degrees.

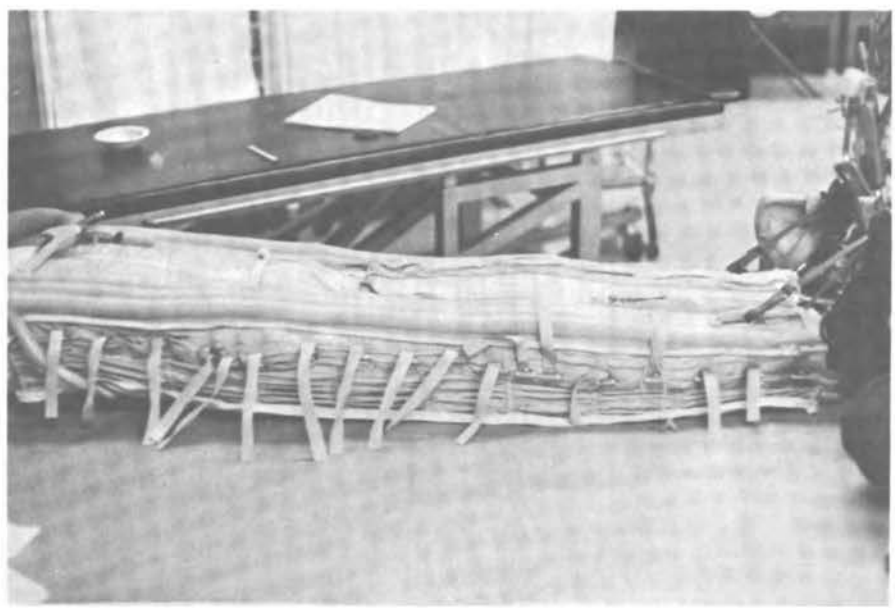

Fig. 2. Adjustment straps individualize the fit of the orthosis. Usually, these straps need to be readjusted about three times after the initial fitting.

A final alignment check is made when the patient is standing, and two or three additional fitting adjustments are usually required before an acceptable fitting is obtained.

Wearers of the orthosis may then don it by positioning themselves over the outspread orthosis, attaching the heel straps and closing the long- and short-leg zippers and the abdominal zipper (Fig. 3). They then turn on the air compressor, which should be positioned close to the patient,

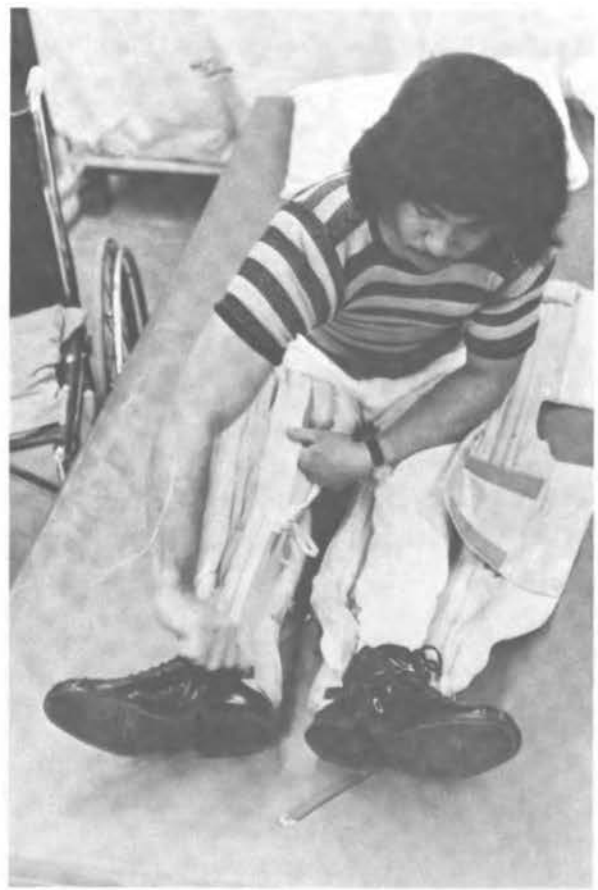

Fig. 3. Patient donning the orthosis. The orthosis is first spread out on a bed and then the patient positions himself over it.

and clamp the inflation hose to the corresponding valve on the orthosis. Once the orthosis is inflated to the recommended pressure of 32 pounds per square inch (psi), as noted on a gauge on the compressor, the inflation hose is removed. The patient can then push himself to the end of the bed and uses crutches to push up to a standing position (Fig. 4). An alternate technique is to inflate the orthosis while in a sitting position and pull up to a standing position by grasping parrallel bars (Fig. 4). A drag to, swing to, or swing through gait can be used. A four point gait is difficult, if not impossible, to achieve.

Fig. 4. Patient transferring from a sitting to a standing position during inflation by pulling himself up using the parallel bars and one crutch.

In order to deflate the orthosis the wearer positions himself ready to sit in a chair or lay on a bed, opens the deflation valve, and slowly lowers himself.

The orthosis may be worn deflated in a sitting position for the entire day.

Wearers of the pneumatic orthosis are cautioned to avoid burning the material, and to keep sharp objects away from the material.

The orthosis may be washed by hand using a mild detergent, and should be inspected periodically for tears, broken stitches or abraded fabric. The orthosis is mailed back to the supplier whenever repairs are needed.

THE PURPOSE AND ORGANIZATION OF THE EVALUATION

The primary purpose of the clinical evaluation was to determine the indications, training needs, advantages and disadvantages of the pneumatic orthosis in the hospital, home, and community. The results of the study are to be used by the Veterans Administration and the Department of Health, Education, and Welfare to determine policy, by educational institutions as instructional material and by medical and paramedical practitioners as a guide for patient management.

A steering committee was formed which met in New York on May 1, 1974. The members of the committee were Heiner Sell, M.D., Assistant Director, and Meg McGarrity, Physical Therapist, Institute of Rehabilitation Medicine, New York; Maurycy Silber, M.D., Director of Rehabilitation, and Nancy Hivry, Physical Therapist, Bird S. Coler Hospital, New York; Thomas Pirrello, Jr., Orthotist-Prosthetist, Veterans Administration Prosthetics Center, New York (Appendix A).

At the steering committee meeting the evaluation participants were chosen, the protocol and timetable were set, and other logistical matters were discussed.

EVALUATION CENTERS

The evaluation was a cooperative effort between VA and civilian hospitals. Centers were chosen for various reasons, e.g., past cooperation with CPRD or VA, proximity to another participating hospital of the opposite category (i.e., VA and civilian), or, simply, expression of interest in the study.

The centers were:

<u>VA Spinal Cord Injury Services</u>

Miami VA Hospital	- Jorge Jacobi, M.D. David Dupree, C.P. Evelyn Carrasquillo, P.T. Betsy Powers, C.C.T.
Richmond VA Hospital	- Charles Lamb, M.D. Hallie Ratliffe, Orthotist Daniel Kahsar, R.P.T.
Hines VA Hospital	- David Stern, M.D. Wilbur Pearson, C.O. Helaine Hull, R.P.T.
Palo Alto VA Hospital	- Inder Perkash, M.D. Maurice LeBlanc, C.P. Deborah Wilson, P.T.

<u>Civilian (non-VA) Evaluation Centers</u>

University of Miami (Jackson Memorial)	- Jerry Enis, M.D. William Sinclair, C.P.O. Robin Smith, R.P.T.
Northwestern University (Rehabilitation Institute of Chicago)	- Bupend Agrawal, M.D. David Thullen, C.O. Steve Huber, R.P.T.
Craig Rehabilitation Hospital	- Harry Hahn, M.D. Alton Scott, C.P.O. Joan Polack, R.P.T.

PROTOCOL

Both specific and general guidelines for patient selection were made.

Specific Criteria:

1. Patients had complete spinal-cord lesions.
2. The etiology was trauma.
3. The lesions were between the T_1 and T_{12} vertebral levels.
4. Severe deformities of the limbs (over 20 degrees) were contraindications.
5. Patients were selected for size and weight to fit the standard-size Ortho-Walk.
6. Patients were inpatients while being fitted and trained.

General Criteria:

1. A sample of patients should be ready for discharge during the study so an evaluation in both the hospital and home setting is possible.
2. A sample of patients who have had previous experience with conventional metal orthoses would be desirable.

Number of Fittings

The Veterans Administration was to provide up to 35 pneumatic orthoses for evaluation. A pair of orthopaedic shoes, and an AC and DC compressor were provided with each orthosis. Each of the seven clinics was therefore allowed up to five orthoses. In cases when a patient would not be using his orthosis, other patients could be fitted with it. A minimum of 35 patients were to be evaluated.

Orientation Session

All participants of the evaluation met in New York on July 1-2, 1974. The guidelines were explained to the group, and a final draft of the evaluation form (Appendix B) was made. The orthotists and therapists were then

taught fitting and training by Dr. Silber, Nancy Hivry, and Melvin Bailey of Bird S. Coler Hospital, and Meg McGarrity of the Institute of Rehabilitation Medicine. The facilities and patients at Coler Hospital were used for the training sessions (Appendix C).

Clinical Trials

The first patients were fitted approximately six weeks following the orientation session. Site visits were made to each center by the CPRD staff, and in two cases by the staff of ILC Dover.

It was apparent that the protocal was too rigid for some of the centers since they were not able to recruit patients. In one spinal-cord-injury center with 160 beds, over 100 patients were quadriplegic. Of the remaining number of paraplegics, over half were hospitalized for pressure sores and most of the remainder were in for urinary problems, surgery, or would soon be moving to a distant city. Only three patients could be recruited in this center during the first few months of the evaluation, despite the fact that it had more beds for spinal-cord-injured patients than the other centers. The protocol was relaxed in order to allow outpatients who could come in for daily therapy to be included.

An interim meeting was held in Miami, Florida, on December 15, 1974. One participant from each center attended this meeting. At this time, six and one-half months into the evaluation, 35 patients had been fitted. Many problems and misunderstandings were taken care of and the date of the final meeting was set (Appendix D).

DATA ANALYSIS

In February, 1974, all centers were requested to send in the completed evaluation forms. The data was then tabulated and prepared for the final meeting.

Number of Patients — Total 37

VA Spinal Cord Injury Centers

Miami	5 patients
McGuire (Richmond)	5
Hines (Illinois)	6
Palo Alto	7
Total	23

Civilian (non-VA) Rehabilitation Hospitals

University of Miami	5 patients
Northwestern (Chicago)	5
Craig (Denver)	4
Total	14

Sex

Males	31
Females	6

Height

Average	5 feet 9-1/2 inches
Range	5 feet 3 inches - 6 feet 2 inches

Weight

Average	144 pounds
Range	98 pounds - 185 pounds

Age

Average	31.6 years
Range	18 years - 58 years

Age of Injury

Time from date of injury to fitting with the pneumatic orthosis.

Average	38 months
Average excluding three oldest injuries	19 months
Range	1 month - 27 years, 9 months

Lesion Level

T-1	3 patients	T-7	-0- patients
T-2	1	T-8	3
T-3	3	T-9	3
T-4	4	T-10	6
T-5	2	T-11	3
T-6	4	T-12	4

No response - 1

Etiology

Trauma	34	
Gunshot wounds		11
Auto accidents		8
Motorcycle accidents		2
Tractor accident		1
Explosion		1
Fall		1
Not specific		10
Total traumatic		34
Tumor		1
Multiple Sclerosis		1
No response		1
Total non-traumatic		3

Decubitus Ulcers (Present before fitting)

Gluteal fold	2
Sacral	1
Sacral and Ischial	1
Coccygeal	1
Total	5

Medication (Valium and/or Dantrium)

Total using daily medications - 17 patients

PHYSIOLOGICAL EFFECTS

Blood Pressure and Pulse Rate

Each center was requested to take blood pressure and pulse rate measurements with the patient supine and standing, without the orthosis and then with the orthosis. Three patients were not able to reach an upright position on the tilt table without the pneumatic orthosis, before orthostatic hypotension would cause dizziness and an average blood pressure of 92/75. However, with the orthosis on, all three patients were able to reach a 90-degree upright position with a stable blood pressure averaging 113/79 with no sign of dizziness. On one patient the pulse rate decreased by 20 pulses per minute when the orthosis was worn, but the change was inconsequential on the other two patients.

On 17 patients the blood pressure, with the orthosis on in a standing position, rose an average of 4 mm Hg when compared to the readings taken in the same position with the orthosis off. The averages were 117/79 mm Hg with the orthosis off and 121/84 mm Hg with the orthosis on. Average pulse rate on the same 17 patients decreased from 89 to 87 pulses per minute when the orthosis was worn. The comparative blood pressure and pulse rate data was consistent throughout the evaluation, i.e., the blood pressure increased slightly with the orthosis on, and the pulse rate remained stable.

Decubitus Ulcers

Five patients with decubitus ulcers were fitted with the orthosis. There were no complaints concerning retarded healing or aggravation of these ulcers, and no indication that they healed faster in the orthosis. No ulcers were caused by the pneumatic orthosis during the evaluation, even though redness over the knee was noted on many occasions.

Bowel and Bladder Function

Clinics were requested to make general observations concerning bowel and bladder function and catheterization attributable to the orthosis. The orthosis seemed to have no effect on bowel or bladder movements, or on the type of catheterization used.

Pain

One patient could not wear the orthosis because it hurt her back, and another complained of bruises acquired while wearing it. All but three of the other patients felt that the orthosis was immediately comfortable. However, these three patients felt that the orthosis was comfortable after wearing it from 15 to 30 minutes. For two patients with back pain, the orthosis offered considerable relief; one also had scoliosis, so the trunk support was of great benefit.

Spasticity

Two patients reported relief from severe spasticity while wearing the orthosis, although they also stated that the spasticity recurred in a greater than normal amount after the orthosis was removed. In two cases excessive spasticity caused the patients to reject the pneumatic orthosis. Adduction contractures in another patient could not be adequately controlled. Spasticity of the hip flexors kept a second patient off balance to such an extent that he was exhausted after ambulating only ten yards. In general, patients felt that their spasticity was slightly decreased while wearing the orthosis.

Heat

One patient rejected the orthosis because he felt it was "too hot." Another preferred to wear it only on cool days. Five complaints concerning heat retention were made.

ORTHOTIC INFORMATION

Fitting and Adjustments

All orthoses were the Ortho-Walk Type B, three-tube standard suits. The length of time to measure patients for the orthosis ranged from 15 to 30 minutes, and averaged 20 minutes. Fitting times ranged from 20 minutes to two hours, and averaged 50 minutes. Three readjustments are usually needed, and can be done by either the therapist or the orthotist. The average time needed per adjustment is 20 minutes, or a total of 60 minutes for all three. However, some patients needed no readjustments while others needed up to five, and in one case three hours and 20 minutes were spent readjusting the laces.

The reasons readjustments are needed are usually 1) the patient was fitted while supine and the fit changes when he stands, and 2) the laces and straps are new, and "give" slightly when stressed. The most common clinical indication that a readjustment is needed is bending at the knees and/or hips, which can be corrected by either tightening the laces and/or placing special pads in the area of the instability.

Equipment

In all cases but one, the orthoses and compressors were received from the manufacturer in excellent condition. In one case, a suit was returned because of a leak, although the manufacturer stated he could not find the leak. In two other cases, at different clinics, a slow loss of pressure (5 psi lost in 10 minutes) was reported. A possible cause for the pressure problems was the high altitude, since most of these problems occurred in Denver. Another patient caused a leak after burning through the fabric of the orthosis with a cigarette. In no instance did a loss of pressure occur so suddenly that the safety of the patient was jeopardized.

The most common and most serious equipment failure concerned the zippers. In five cases the seam attaching the zipper to the nylon fabric failed. In one case the zipper came off track. The zipper failures were sudden and caused one patient to fall. Another patient had a zipper give way while he was training to descend stairs. The therapist fortunately caught him.

Equipment repairs were made by ILC Dover. All repairs were made satisfactorily, but the length of time required for shipping the orthosis back and forth and for repairs ranged from two to four weeks. Two patients lost interest in the evaluation while their suits were being repaired.

Previous Orthotic Experience

Twelve patients were using metal orthoses prior to the evaluation. Five patients were ambulatory and the remaining seven used them for standing only. Patients wearing orthoses spent from eight to ten hours daily in bed, from two and one-half to three hours standing, and the remaining time sitting. Patients who had not been fitted spent an average of 15 hours daily in bed and nine hours in a chair.

Four patients had an inadequate range of motion. One patient who had bilateral 15-deg knee-flexion contractures and a 10-deg limitation of ankle dorsiflexion was fitted and did well in the orthosis. Another patient with a 30-deg hip-flexion contracture could not stand independently in the orthosis and could ambulate only at great energy expense, but kept the orthosis as a therapeutic device.

THERAPY INFORMATION

Inflation, Standing, Transfers

Seventeen patients preferred to inflate the orthosis while they were in the supine position, and then push themselves over the edge of the bed

until their feet contacted the floor. They then grab one crutch, push themselves upright, and pick up the second crutch.

Sixteen patients preferred to inflate the orthosis while they were sitting and either pull themselves up by grasping parallel bars or push themselves up by turning around in front of the wheelchair and pushing up from the armrests. Three patients were brought to 90 degrees on the tilt table before inflating the orthosis.

Joint Stability

Three patients did not receive enough trunk support, and 11 patients did not have enough knee stability (Fig. 5). The normal posture in the pneumatic orthosis differs considerably from the extended posture seen with metal orthoses. The trunk and hips are in a neutral position in the Ortho-Walk, rather than extended, and the knees stay slightly flexed. This different type of posture undoubtedly caused many to think that inadequate stability was provided.

Seven patients thought the lack of ankle stability was a problem. The Ortho-Walk prevents plantarflexion by having an anterior strap extend to the shoe laces, but allows free dorsiflexion.

Time and Distance

Patients wore the orthosis for an average of 20 minutes a day deflated, and 30 minutes a day inflated. The average distance traversed was 54.0 yards in 24 minutes, or 6.75 feet per minute. One patient, however, covered 300 yards in 45 minutes, which is a rate of 20 feet per minute. This patient was 5 feet 11 inches tall, weighed 160 pounds, 26 years of age and was able to press 260 pounds when weightlifting.

Fig. 5. Instability of the knees and hips. Although only two or three patients had this much instability, 11 patients cited this as a major problem. The addition of pads, re-adjustment of laces, or use of a four-tube suit may help to correct this problem.

Donning and Doffing

Twenty-three patients were able to don the orthosis independently; seven needed major assistance and three needed minor assistance. The time needed to don the orthosis ranged from eight to 60 minutes and averaged 25.5 minutes.

Twenty-seven patients could doff the orthosis independently; two needed major assistance and five needed minor assistance. The average time needed was nine minutes and ranged from three minutes to 20 minutes.

Fifteen patients could independently don clothes over the orthosis; three needed assistance.

Transfers, Stairs, Recoveries

Transfers from a sitting position to a standing position were made independently by 18 patients. Fourteen needed assistance. Approximately five therapy sessions of 30 minutes each were needed before patients could transfer independently. All but six patients could deflate from a standing position independently. Patients were able to achieve this after about four therapy sessions of 20 minutes duration.

No patients were able to climb stairs independently, although seven could climb them with assistance. Six patients could handle a six-inch step or curb independently.

Eight patients attempted to learn fall recoveries, but only one could recover independently. He achieved this by first unfastening the abdominal zipper of the orthosis, then jacknifing and climbing his walker.

Gait Patterns

The most commonly used gait pattern was the "swing to" pattern, which 17 patients adopted. Nine preferred the "drag to" and nine used the "swing through" pattern (Fig. 6).

Fig. 6. Patient learning the "swing through" gait pattern at Coler Hospital, New York.

ACCEPTANCE

Fourteen of the 37 patients chose to accept the orthosis for regular, if in some cases limited, use. The remaining 23 rejected it.

All of the patients accepting the Ortho-Walk were males. The average age of this group was 34 years, whereas the average age of those rejecting the orthosis was 30 years.

The height and weight of the patients accepting the orthosis averaged 69.6 inches and 141.5 pounds. Four of the patients were described as having normal body builds, four were listed as thin and six were muscular. All three patients who were considered obese rejected the orthosis. The average height of patients rejecting the orthosis was one-half inch less than those accepting it, and the average weight of those who rejected it was four pounds greater.

The age of injury (time from date of onset of paraplegia to fitting with the Ortho-Walk) for patients who accepted the pneumatic orthosis was two years less than those who rejected it (23 months versus 47 months).

The average lesion level for patients who accepted the Ortho-Walk was T_8 - T_9, whereas the level of those who rejected it was T_5 - T_6.

The follow-up time for all patients was from one month to eight months. Two of the patients who were only followed for one month were listed as accepting the orthosis.

Of the 23 patients who rejected the orthosis, the most common reasons for rejection were excessive energy consumption and inadequate stability at the knees, hips, and ankles. Two patients needed to have their ankles bound together in a "hobble" to prevent their legs from abducting excessively (Fig. 7); lack of motivation rated next as the reason for rejection. The motivational problems generally occurred once the patient realized the amount of effort required for standing and ambulation. Four patients started out highly motivated, but were listed as having poor motivation when they rejected the orthosis.

Poor cosmesis was listed as the reason for rejection by three patients, who stated that the thoracic section was too bulky, and that wearing clothes over the orthosis was impractical (Fig. 8).

Fig. 7. A "hobble" around the ankles was needed on two patients to prevent the legs from spreading apart an excessive amount.

Six patients preferred their metal knee-ankle-foot orthoses (KAFO'S) to the Ortho-Walk, and in three cases the reverse was true. Of the six preferring the metal KAFO'S, three patients used the Craig-Scott (6) design orthosis and three used conventional designs.

Three patients listed donning problems as one reason for the orthosis being rejected. These patients had higher lesions (T_4) and it took them from 25 - 60 minutes to don the orthosis independently. With assistance, the donning time was considerably shortened.

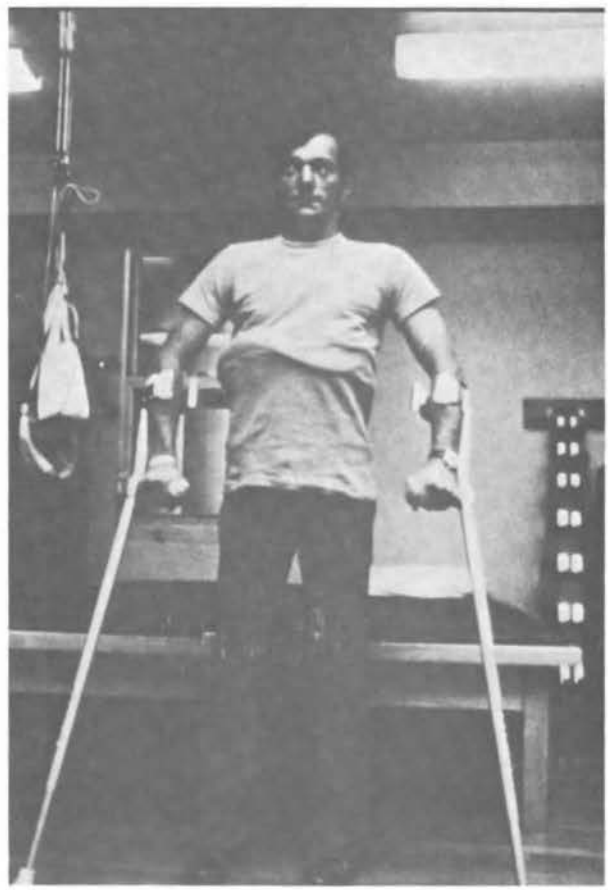

Fig. 8. Patient wearing clothes over the Ortho-Walk. Three of the patients who rejected the orthosis complained about the cosmesis.

Ten patients took the orthosis home. Of these ten patients, two use it daily outside of the household, for school, work, and social activities. Three of these patients use the orthosis daily for household ambulation. Of the remaining five patients who took the Ortho-Walk home, one uses it two to three hours a week in the kitchen; another uses it one hour a day for exercise; one patient uses it once a week for 30 minutes of exercise, and two patients use it rarely, i.e., about once a month.

TABLE I: PATIENTS ACCEPTING THE ORTHO-WALK PNEUMATIC ORTHOSIS

	Initials	Sex	Age	Height	Weight	Age of Injury	Level of Injury	Previous Orthotic Experience	Comments
1	J.A.	M	25	68"	---	5 mos.	T 12	None	Only followed one month, good progress
2	S.B.	M	58	68	165	5 mos.	T 9	None	Therapeutic use in hospital
3	T.C.	M	26	73	158	5 mos.	T 6	None	Household ambulator, good motivation, provides good trunk control. Zippers pulled apart
4	L.D.	M	36	72	138	7 mos.	T 10	New KAFO'S	Household ambulator, complains of heat. Needs feet tied together to prevent abduction
5	L.B.	M	36	72	117	14 mos.	T 12	KAFO'S ambulatory	Prefers Ortho-Walk to metal KAFO'S. Alleviates back pain, more ambulatory. Uses in home one hour/day for exercise
6.	O.W.	M	28	71	156	5 mos.	T 8	None	Spasticity, back pain decreased. Ambulatory with walker. Four tube suit required. Prefers "Stand-Alone device."
7.	J.C.	M	39	65	120	58 mos.	T 3	KAFO'S,2 yrs. ambulatory with standing assist	Therapeutic use in hospital. Decreases spasticity. Needs assistance. Difficult donning. Better trunk stability. Prefers metal KAFO'S
8.	R.F.	M	44	66	130	42 mos.	T 10	None	Highly motivated. Psychological advantage to standing. Household ambulator.
9	B.B.	M	26	71	160	18 mos.	T 11	None	Impractical for ambulation due to excess energy expenditure. Therapeutic & psychological advantages standing. 30^{0} hip flexion contractures. Uses once a week for 30 minutes
10	R.J.	M	25	71	145	36 mos.	T 4	None	Positive attitude. Good trunk support. Independent ambulator with crutches. Wears it to school and socially
11	E.D.	M	57	74	185	149 mos.	T 4	Metal KAFO'S for 5 yrs., then lost trunk musculature. Out of orthosis for 12 yrs.	First orthosis to provide adequate trunk support. Good attitude. Uses at home and office daily.
12	B.S.	M	21	74	180	12 mos.	T 6	KAFO'S used only once	Dependent with suits. Prefers the metal KAFO'S. Heterotrophic bone formation at hips. Zipper pulled apart. Rarely uses suit.
13	R.M.	M	20	69	150	1 mo.	T 4	None	Uses only once a month. Difficulty donning. High energy cost.
14	F.N.	M	37	70	157	3 mos.	T 8	None	Zipper pulled apart, problems donning. High energy cost. Uses 2-3 hours a week, mainly in the kitchen.

TABLE II: PATIENTS REJECTING THE ORTHO-WALK PNEUMATIC ORTHOSIS

	Initials	Sex	Age	Height	Weight	Age of Injury	Level of Injury	Previous Orthotic Experience	Comments
1	S.J.	M	23	73"	135	7 mos.	T 4	None	Adductor spasms, 15^0 hip flexion contractures
2	M.O.	M		70		14 mos.	T 1	None	Not functional. Emotional problems, committed suicide.
3	W.D.	M	45	73	158	21 yrs. 6 mos.	T 6	KAFO'S for exercise	Easier than metal KAFO'S. Patient not motivated to use either type.
4	K.C.	M	18	72	160	7 mos.	T 2	None	Poor cosmesis, problem with standing balance.
5	G.D.	F	27	63	130	4 mos.	T 9	None	Poor attitude. Poor cosmesis. Not considered practical by the patient.
6	M.L.	M	29	71	140	8 mos.	T 9	None	Poor cosmesis. Excessive energy. Didn't like the "hassle."
7	J.B.	F	36	67	137	4 mos.	T 5	Craig-Scott KAFO'S 3-4 weeks Stand only.	Limited transfer function. Suit deflated. Tried only three times and patient lost interest.
8	M.G.	M	24	71	113	23 mos.	T 1	Craig-Scott KAFO'S 8 mos. Functional ambulation	Preferred ankle stability from metal orthoses. Problems donning and doffing.
9	L.J.	M	18	66	119	3 mos.	T 12	Craig-Scott KAFO'S 2 mos. Ambulate with assistance	Poor cosmesis with clothes over it. Needs two assistants.
10	G.R.	F	21	63	144	2 mos.	T 5	None	Knee flexion problems. Suit deflated. Donning, doffing problems
11	R.M.	M	28	66	105	26 mos.	T 6	KAFO'S 2 yrs. Stand only.	Left hospital ambulatory in orthosis but no longer uses it.
12	K.T.	M	27	70"	155	1 mo.	T 4	None	Poor attitude. Lack of acceptance of injury.
13	J.K.	M	50	71	160	28 yrs	T 12	Metal KAFO'S 26 yrs. Independent.	Restricts hip motions, jacknifing prefers metal
14	J.W.	M	48	69	161	6 mos.	T 4	None	Excessive energy cost, donning takes 20 minutes
15	M.H.	F	22	62	98	18 mos.	T 10	None	Excessive energy cost. Patient highly motivated but too much effort.
16	D.R.	F		69		6 yrs.	T 1	Rejected KAFO'S with pelvic band after six months	Inadequate knee support. Poor cosmesis. Decreased spasticity but caused swelling.
17	E.J.	M	44	65	160		T 10	None	Zippers broke and patient lost interest after repairs made.
18	R.P.	M	32	70	164	4 yrs.		None	Too much trouble
19	P.P.	M	31	70	170	8 yrs.	T 8	KAFO'S, 2 yrs.	Prefers metal KAFO'S
20	M.A.	M	22	72	120	16 mos.	T 10	KAFO'S, 2 mos. Independent Ambulation	Difficult to climb stairs, curbs, prefers metal KAFO'S.
21	F.D.	M	39	73	170	4 mos.	T 12	None	Suit too small, poor motivation
22	P.G.	M	19	70	115	6 mos.	T 12	None	Used in hospital for standing only. Disinterested.
23	R.G.	F	31	66	110	8 mos.	T 10	None	Took suit home and used it, but then rejected it in favor of metal KAFO'S.

In summary, patients who accepted the Ortho-Walk pneumatic orthosis were those in good physical condition with thin to muscular builds. A positive attitude towards standing and ambulating, combined with good motivation, also appeared to underlie energy acceptance. Perhaps these patients experienced a significant psychological boost from being upright, which justified for them this relatively inefficient technique of standing and ambulating.

It should also be noted that only those patients who fitted into the standard Ortho-Walk-size range were selected for the study. If a random selection process had been used, a larger number of patients would have fallen outside the average height and weight range (69.6 inches and 141.5 pounds) of those patients accepting the orthosis; and, therefore, a higher rejection percentage would have resulted.

COMPARISON BETWEEN VA AND NON-VA PATIENTS

The average age of VA patients in the study was 8.8 years greater than that of non-VA patients (35.6 years vs 26.8 years), mainly because there were five VA patients who were 45 years of age or older, with long-standing injuries. None of the non-VA patients were of this age. Ages of injuries were also highest in the VA groups, averaging 51 months vs 11 months for non-VA patients. Older patients with long-standing injuries were more prevalent in the VA population because they generally kept in closer contact with the local VA hospitals, were aware that the study was going on, and requested to be participants.

Ten of the 23 VA patients, or 43 percent, accepted the pneumatic orthosis for the trial period, while only four of the 14 non-VA patients (28 percent) accepted it. The probable reason for the slightly higher acceptance rate at VA hospitals lies in the longer period of training they provided and their general tendency to be freer with their time. The private hospitals had problems financially justifying long training sessions over many weeks. Also, a few of the VA patients who were listed as accepting the orthosis

were still in training at the end of this study, and may have rejected it later. In general, the private hospitals provided less training and discharged patients earlier than VA hospitals.

CONCLUSIONS

On March 17-18, 1975, all participants of the evaluation met at Craig Rehabilitation Hospital in Englewood, Colorado, to discuss the results of the evaluation (Appendix E). The participants met in a plenary session, then divided into three groups: physicians, therapists, and orthotists, to draw conclusions and make recommendations from the evaluation.

No age limit was set for patients who wish to use the orthosis, but the height and weight were determined to be crucial factors. The participants agreed with the manufacturer that patients taller than six feet and in excess of 160 pounds require a four-tube suit instead of the standard three-tube design. Patients who are obese will have a minimal success rate and should have a custom suit designed if a good fit and proper support is to be expected. Patients with thin to muscular body builds have the best chance to achieve functional standing and walking.

People who work or study seem to make more use of the Ortho-Walk because of their desire to be active. Lack of accessibility to wheelchairs on a job, or employment requiring a standing position are both indications for lower-limb orthoses, including the Ortho-Walk design.

Patients who need to be very mobile, i.e., in and out of cars, planes, different businesses, will generally be hampered by lower-limb orthoses. The Ortho-Walk is contraindicated for these people due to the problems with inflation, deflation, and transfers.

Previous orthotic experience does not seem to affect the acceptance of the pneumatic orthosis, as six patients who wear metal KAFO'S preferred them to the Ortho-Walk, but the reverse was true for three patients. All

patients who use the Ortho-Walk outside of the hospital should also be wheelchair independent. It was recommended that patients having success with previous orthoses are doing well enough and should not be encouraged to change to the Ortho-Walk.

The etiology of the lesion did not affect the results in the orthosis, nor did the level of the lesion. In fact, of those who accepted the orthosis, the three patients with the highest lesions were among the most successful users. More experience is needed with patients with high lesions during the medical stabilization phase before any conclusions can be made about the use of the orthosis in this situation.

A small study at the Miami VA Hospital indicated the Ortho-Walk did aid venous return and increased the blood pressure and volume to the kidneys. Therefore, cardiovascular conditions do not contraindicate the use of the orthosis for standing, but these patients should be watched closely, especially if ambulation is attempted.

The Ortho-Walk did not impair the respiration of any patient, and aided one patient in this respect.

Spasticity is not a contraindication to using the Ortho-Walk. In most cases, patients stated and therapists observed that the severity of spasticity was decreased or eliminated shortly after the application of the pneumatic orthosis.

The presence of decubitus ulcers does not necessarily contraindicate use of the Ortho-Walk. Five patients with decubiti in areas covered by the orthosis did not have any problems, and healing continued at a normal rate. On the other hand, there were indications of substantial increases in pressure under the suit, and (as noted earlier) reddening in several areas was observed after use.

A positive attitude of both the patient and the rehabilitation team is of utmost importance. A negative attitude towards standing or towards the different type of orthosis by the members of the team will quickly pass on to the patient, and the chances of functional standing and ambulation will be decreased.

The orthotists concluded that there were no problems with the recommended measurements, that the range of standard sizes was adequate and that the initial fitting procedure was good. No mechanical problems were encountered with the pneumatic beams, the AC and DC compressors, or the inflation valves. It was recommended that the deflation valve be redesigned so it can be left open, thereby freeing up the patient's hands while the suit is deflating. This would also allow air to continue escaping while the wearer is seated.

Miniaturization of the inflation mechanism was recommended. The portable compressor in the present system is too bulky and heavy to be carried by a paraplegic while he is standing, and the user must have a compressor available any time he wishes to stand. Small CO_2-type cartridges have been used in the past with minimal success, and it is recommended that a similar approach to inflation be perfected.

The donning procedure proved to be one of the major problems with the orthosis. Patients who could don the orthosis independently were often too exhausted to transfer, stand, and ambulate. No solution to this problem could be found during the evaluation.

The lack of a dorsiflexion stop at the ankle caused a few patients to feel unstable, and made it necessary for patients to use crutches when standing. Patients who expect to use the orthosis outside of the hospital for functional standing should also receive ankle-foot orthoses to provide anterior stability at the ankles.

PRACTICALITY FOR THERAPEUTIC USE

The Ortho-Walk pneumatic orthoses are practical for therapeutic use in the medical stabilization and rehabilitation phases of patient care in spinal injury when standing and ambulation are desired goals. Certain temporary psychological advantages seem to be offered, and it provides the rehabilitation team with one method of evaluating a patient standing before any further orthotic prescriptions are made. The adjustability and modularity of the suits allow them to be used on many patients. A stock of three to six suits can be fitted to most patients.

It is recommended that, whenever possible, any patient who may be a candidate for the Ortho-Walk receive a minimum of 40 hours of physical therapy in a stock suit of the correct size before a suit is ordered specifically for him.

PRACTICALITY FOR HOME AMBULATION

The Ortho-Walk Type B pneumatic orthosis has no real advantages over conventional orthoses in functional ambulation. The advantage of light weight is offset by the inconvenience of inflation and deflation, and the added difficulty of climbing stairs and recovering from falls. For use on level surfaces in the home, the Ortho-Walk has proved to be practical.

PRACTICALITY FOR COMMUNITY AMBULATION

The Ortho-Walk pneumatic orthosis has no real advantages over conventional orthoses for community ambulation. In the community, the disadvantages of the inflation system and of cosmesis are more apparent than in the home. The user must either have a number of compressors strategically located in the home, car, office, or school, or have an assistant carry a compressor with him. The noise of the compressor when inflating and of air escaping when deflating has drawn attention to the user of the orthosis in public places.

SUMMARY AND RECOMMENDATIONS

Based upon data collected from seven hospitals and 37 paraplegic patients with thoracic lesions, the following conclusions and recommendations were made concerning the Ortho-Walk Type B pneumatic orthosis.

ADVANTAGES

- Less weight than conventional orthoses.
- Temporary positive psychological reaction.
- Cost is reasonable when used as stock item on many patients.
- Adjustability and adaptability allows rapid application in the early treatment phase.
- Possible energy expenditure savings during ambulation.
- Adequate trunk support.

DISADVANTAGES

- Difficult and time-consuming to don.
- Inflation-deflation system is impractical.
- Provides less support to lower limbs than conventional orthoses.
- Cosmesis is poor, especially for women. Conventional orthoses are more cosmetic.
- Mobility is decreased. Stair-climbing and transfers are more difficult than with conventional orthoses.
- Maintenance and repairs must be made by the manufacturer, necessitating long waits due to mailing time.
- Cost is higher than conventional orthoses when used for one patient only.

RECOMMENDED IMPROVEMENTS

1. Improvement of the inflation-deflation system by miniaturizing the pressure source. An alternative solution may be the addition of knee and hip joints.

2. More ankle stability be provided, specifically to prevent dorsiflexion.

3. Ventilation of the suit.

4. The color of the suit (blue) is not cosmetic and could be improved.

RECOMMENDATIONS FOR FUTURE STUDIES

1. A study of the pressures at the interface between the pneumatic suit should be made. Redness usually occurs over bony areas when the suit is worn and clinicians are fearful that long-term standing may lead to skin breakdown.

2. More basic bioengineering is needed if pneumatic orthoses are to be made practical and be universally accepted.

3. Evaluation of other systems of mobilizing paraplegic patients should be made, such as that undertaken by Lehman *et al.* (6) on the Craig-Scott design knee-ankle-foot orthosis, which is used successfully in the Denver area. A quantitative study would be useful to compare pneumatic orthoses with standard knee-ankle orthoses used in paraplegic ambulation.

4. A careful study should be done to verify and document reported psychological and physiological benefits accruing from the use of various orthoses.

CONCLUDING STATEMENT

The concluding statement of the participants in the evaluation was that the Ortho-Walk Type B pneumatic orthosis has the potential for being a tool in the early rehabilitation of spinal-cord-injured patients. Its relative adaptability and ease of use in the early rehabilitative phase has the advantages of a temporary psychological lift, early screening of potential candidates for orthoses, and possibly aiding and improving the

physical status of these patients. When considering candidates for the pneumatic orthosis, individualization of patients is a must, just as with conventional orthoses.

This study has shown that, as with all new ideas, the Ortho-Walk is not a panacea. Many improvements must be made before it can equal the merits of conventional metal orthoses. The idea of pneumatic splinting for paralyzed people is a feasible one, but it still needs much work. The fact that a private manufacturer can research, develop, and market such an innovative device without outside support is an accomplishment in itself. Ideas such as the Ortho-Walk can stimulate research teams in different disciplines to work jointly for the ultimate goal of better care for the spinal-cord-injured patient.

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AGENDA

STEERING COMMITTEE MEETING FOR THE EVALUATION
OF THE ORTHO-WALK PNEUMATIC ORTHOSIS

SUBCOMMITTEE ON EVALUATION
COMMITTEE ON PROSTHETICS RESEARCH AND DEVELOPMENT
NATIONAL ACADEMY OF SCIENCES

Veterans Administration Prosthetics Center
252 Seventh Avenue
New York, New York
May 1, 1974

Wednesday, May 1, 1974	10:00 a.m.
Welcome	Anthony Staros
Purpose of Clinical Evaluation	A. Bennett Wilson, Jr.
Present Status of the Ortho-Walk Orthosis	
Description	
Experience at Bird S. Coler Hospital	Maurycy Silber
Experience at IRM Hospital	Heiner Sell
Prescription Criteria	
Areas of Study in the Evaluation	
Selection of Patients	
Number of Patients Involved	
Selection of Evaluation Centers	
Evaluation Procedure and Timetable	
Evaluation Forms	
Peripheral Studies	

MINUTES OF STEERING COMMITTEE MEETING
ORTHO-WALK PNEUMATIC ORTHOSIS EVALUATION

SUBCOMMITTEE ON EVALUATION
COMMITTEE ON PROSTHETICS RESEARCH AND DEVELOPMENT
NATIONAL ACADEMY OF SCIENCES

Veterans Administration Prosthetics Center
New York, New York
May 1, 1974

Subcommittee Member Present:	G. E. Sharples
Invited Participants:	Francis A. Appoldt Nancy Hivry Margaret McGarrity Thomas Pirrello Heiner Sell Maurycy Silber Anthony Staros Howard R. Thranhardt
Developer's Representative:	Bonnie Baggett
Staff Members Present:	Hector W. Kay Michael J. Quigley* A. Bennett Wilson, Jr.

Veterans Administration Involvement

Mr. Staros opened the meeting by stating the necessity for an evaluation of the pneumatic orthosis in both the Veterans Administration (VA) and civilian hospitals. The VA has been interested in pneumatic orthoses for over two years but previous evaluation attempts have failed to produce the information needed by VA. A recent upsurge of interest in both pneumatic orthoses and rehabilitation further necessitated the need for a full-scale evaluation as soon as possible. Positive evaluation results would make it possible for VA to provide these orthoses to patients because the indications, training needs, advantages and disadvantages of the pneumatic orthosis would then be proven and documented.

*Mr. Quigley chaired in the absence of Frank W. Clippinger, Jr., Chairman.

Mr. Staros also stated that a purchase order for 40 suits for evaluation purposes had been made through the ILC Dover Company, the sole manufacturer and distributor of the orthoses.

NAS-NRC-CPRD Involvement

Mr. Wilson explained the role of the National Research Council (NRC) in the evaluation. Coordination and design of the evaluation by the staff of the Committee on Prosthetics Research and Development (CPRD) is the major role as well as preparing the final report. Mr. Wilson outlined the evaluation procedure that has been used successfully by CPRD in the past and stated that Mr. Quigley would be the responsible staff member for this evaluation.

He also mentioned that the evaluation should be limited to one type of patient and that about five pneumatic suits per center would provide us with adequate information, while remaining logistically feasible.

Evaluation Centers

The evaluation is to be a cooperative effort between VA hospitals and civilian hospitals. The centers were chosen for a number of reasons including past cooperation with CPRD or VA, expressed interest in the evaluation, an attempt at a "sister" study (one VA, one civilian hospital in the same city), and an unbiased view of the evaluation.

VA Spinal Cord Injury Services

Miami VA Hospital
Richmond VA Hospital
Hines VA Hospital
Palo Alto VA Hospital

Civilian Evaluation Centers

University of Miami
Northwestern University
Craig Rehabilitation Hospital

It was suggested that Peter Hofstra, Director of VA Spinal Cord Injury Services, would be contacted regarding the role of the VA Hospitals in the evaluation.

A clinic team from each center consisting of a physician, physical therapist, and orthotist will be the responsible investigator in the evaluation.

Orientation Session

An orientation session will be held in early July. The session will last two to three days. The members of each clinic team will attend. The first day will be devoted to an explanation of the evaluation procedure and forms, the uses of the orthosis, and indications. The second and third days will involve the therapists and orthotists only. They will be trained in the measuring, fitting, and training procedures at Bird S. Coler Hospital.

Equipment Procurement

All equipment (orthoses, shoes, compressors, undergarments) will be provided through Donald Wright of the VA Prosthetics Center. Centers will be provided with up to five suits for the evaluation. Each center will take patient measurements and forward them to the VA, which will then obtain the suit and send it to the center. Orthopedic shoes will also be provided as a necessary part of the orthosis. The one style is available in both brown and black colors.

Patient Selection

Some general guidelines for patient selection were made. Since the evaluation should determine the value of the orthosis in both the hospital (therapeutic) setting and the home (domestic) setting, a number of patients in the evaluation should be expected to be discharged from the hospital before the end of the evaluation, so the home setting may be evaluated.

A comparison between pneumatic orthoses and conventional metal orthoses would be desirable in a few cases, so a few patients with previous conventional orthotic experience should be included.

Patients must fit into the range of standard sizes of orthoses.

Patients in the evaluation must be inpatients while being fitted and trained with the orthosis.

Dr. Silber stated that all centers must have the proper philosophy concerning bracing of patients, that is, bracing should be attempted on the vast majority of spinal-cord-injured people He also stated the two distinct but related advantages to bracing and recommended that each area be considered separately. Physiological and psychological benefits from standing and walking are of maximum importance, he stated, and the advantage of mobility and increased function follow naturally once the initial benefits are realized.

Dr. Sell stated that he did not find that the physiological benefits were of any consequence, in his experience, but that patients at the Institute of Rehabilitation Medicine were admitted very early post-trauma, and therefore he did not encounter the complications Dr. Silber had to deal with at Coler Hospital.

It was agreed that the patient population at Coler Hospital is probably the same as at the VA Hospitals and the patient population at the Institute of Rehabilitation Medicine is similar to most civilian rehabilitation hospitals.

Drs. Silber and Sell added the following criteria for patient selection:

- Patients should have complete spinal cord lesions
- The etiology should be trauma
- The lesions must be between T_1 and T_{12} vertebral level
- Severe deformities of the limbs are contraindications
- Unstable vertebral fractures with complete lesions should be fitted at the physician's discretion and an additional spinal immobilization orthosis may be used in this case

Areas of Investigation

The physiological benefits of the pneumatic orthosis, as described by Dr. Silber, would not be practical to evaluate in all of the centers. Mr. Staros stated that there is a need for work in this area and that the VA may be able to support some of this work. Other areas that may need further investigation will probably be determined by the evaluation results.

Areas of investigation fall into four categories, although many areas overlap. Evaluation forms that request this information will be designed.

Medical Information Needed:

Medical History
Blood Pressure - pulse rate difference with/without the orthosis
Decubitus measurement and effect of orthosis on healing time
Effect of orthosis on spasticity
Effect of orthosis on spinal shock recovery time
Psychological effect on patient
Measurement of mild contractures and effect of orthosis on contractures

Physical Therapy and Orthotic Information Needed:

Foot/Ankle Stability
Measurement and fitting experiences
Independent donning and doffing techniques
Independent dressing over the orthosis
Inflation and deflation techniques
Supine to wheelchair transfers
Sitting to standing transfers
Gait training, techniques and time necessary
Endurance, time and distance
Bathroom function
Length of time wearing the orthosis inflated and deflated
Falling and recovery techniques
Compressor portability

Equipment Information Necessary

Size range practicality
Inflation, deflation problems, if any
Lacing and zipper problems, if any
Causes and locations of blowouts
Suit durability and safety, by month
Shoe problems, if any

General Information Needed

Photographs
Monthly or bimonthly progress report
Value of instruction manual

Evaluation Timetable

Mrs. Hivry stated that it takes from one week to two months to determine the success of a patient in the pneumatic orthosis. Two months following the orientation session, a site visit to each center will be made to determine the progress of the center and to help solve problems. A six-month period should be enough time to determine the practicality of the pneumatic orthoses. A final meeting of the

centers may be scheduled in Miami previous to the annual University of Miami orthotics and prosthetics course, with some of the results presented at the course.

Overall Time Schedule

Orientation Session	Early July 1974
Clinical Trials Begin	Late July
Site Visits	September
Final Meeting	December
Evaluation Report	February

NATIONAL ACADEMY OF SCIENCES
COMMITTEE ON PROSTHETICS
RESEARCH AND DEVELOPMENT

Phone : 202 389-6345

ORTHO-WALK EVALUATION

Case:_____

Participating Facility:

APPENDIX B

Coordinator: _____

Case/Patient ID Number: _____

PATIENT IDENTIFICATION

Patient Name: _____ Date of Birth: _____ 19__

Current Address: _____ Usual Occupation: _____

Sex: Male [] Female [] Ht: ___ ft. ___ in. Weight: ___ lbs. Age ___ yrs.

Date of Onset: _____ 19__

Date Admitted: _____ 19__

PRESCRIPTION & DEVICE DESCRIPTION

Dates: Measurements Taken _____ First Fit _____

Size: Standard # _____

Time Used:

Measurement _____ Min. Fitting _____ Min.

Condition on Receipt from Manufacturer: Excellent []

Problems: _____

Fitting - Suit Adequate for Patient Yes []
No: _____

- Shoes Adequate for Patient Yes []
No: _____

- Laces, Straps, Zippers Yes []
No: _____

- Valves Function Yes []
No: _____

- Air Bladder Function Yes []
No: _____

Re-adjustments Needed
After First Fit: # _____ Reasons: _____

Modifications to Suit Needed: _____ Time Spent to Re-adjust _____ Min.

Service Problems: _____

_____ Orthotist Initials ___
Typed Name:

ORTHOTIST

PHYSICIAN

CRITERIA APPLICATION & BASELINE MEASURES

General Physical Condition: Excellent [] Good [] Fair [] Poor []

Lesion Level (functional) T 1 2 3 4 5 6 7 8 9 10 11 12

Etiology: _____ Ulcers Present [] Not Present []

Concurrent Pathologies: _____ Ulcers Location: _____

_____ Ulcers Severity: _____

Medication (Relaxants): _____ Dosage: _____

Body Build/Musculature: Normal [] Thin [] Obese [] Muscular [] Catheter Type: _____

Limitations to Crutch Walking (Arm Problems, Etc.): _____ None []

Prior Experience with Orthosis: No: [] Yes: Type _____

Time with Previous Orthosis: ____ years Function Achieved: _____

Note: ► Average of 3 readings taken 5 mins. apart

	Supine	Standing		Supine	Standing
Blood Pressure Without Orthosis	___/___	___/___	Blood Pressure After Initial Fitting Wearing Orthosis	___/___	___/___
Pulse Rate	_____	_____	Pulse Rate	_____	_____

PHYSICIAN

COMMENTS:

Practicality for this Patient: _____

_____

Advantages for this Patient: _____

_____

Disadvantages for this Patient: _____

_____

Recommendations: _____

_____

_____

ADDITIONAL COMMENTS OR OBSERVATIONS:

_____

_____

_____ Physician Initial: ____

Typed Name:

PHYSICIAN OR THERAPIST

PERIODIC OBSERVATIONS & MEASUREMENTS

Note: Average of 3 readings taken 5 mins. apart

(After 30 Days)	(After 60 Days)	(After 90 Days)
Maximum Tilt Table ____°	Maximum Tilt Table ____°	Maximum Tilt Table ____°
Stand: Aided [] Unaided []	Stand: Aided [] Unaided []	Stand: Aided [] Unaided []
Walk: Aided [] Unaided []	Walk: Aided [] Unaided []	Walk: Aided [] Unaided []
Ulcer Status:	Ulcer Status:	Ulcer Status:
Catheter Type:	Catheter Type:	Catheter Type:
Effect on Bladder Bowel Function:	Effect on Bladder Bowel Function:	Effect Bowel Function:
Blood Pressure and Pulse: Supine Standing	Blood Pressure and Pulse: Supine Standing	Blood Pressure and Pulse: Supine Standing
Without Orthosis ___/___ ___/___	Without Orthosis ___/___ ___/___	Without Orthosis ___/___ ___/___
Pulse Rate ____ ____	Pulse Rate ____ ____	Pulse Rate ____ ____
Wearing Orthosis ___/___ ___/___	Wearing Orthosis ___/___ ___/___	Wearing Orthosis ___/___ ___/___
Pulse Rate ____ ____	Pulse Rate ____ ____	Pulse Rate ____ ____
Medications (Relaxants): No Change [] Changed to:	Medications (Relaxants): No Change [] Changed to:	Medications (Relaxants): No Change [] Changed to:
By: Date:	By: Date:	By: Date:

THERAPIST

PERIODIC PERFORMANCE & EXPERIENCE

(After 30 Days)	(After 60 Days)	(After 90 Days)
Type of Program:	Type of Program:	Type of Program:
Tilt Table [] Standing [] Ambul/Assist [] /Unassist []	Tilt Table [] Standing [] Ambul/Assist [] / Unassist []	Tilt Table [] Standing [] Ambul/Assist [] /Unassist []
Range of Motion:	Range of Motion:	Range of Motion:
R - H ____° K ____° A ____°	R - H ____° K ____° A ____°	R - H ____° K ____° A ____°
L - H ____° K ____° A ____°	L - H ____° K ____° A ____°	L - H ____° K ____° A ____°
Circumf.: (largest) Thigh ____ in	Circumf.: (largest) Thigh ____ in	Circumf.: (largest) Thigh ____ in
Calf ____ in	Calf ____ in	Calf ____ in
Muscle Tone: Flaccid [] Spastic: Severe []	Muscle Tone: Flaccid [] Spastic: Severe []	Muscle Tone: Flaccid [] Spastic: Severe []
Moderate [] Mild []	Moderate [] Mild []	Moderate [] Mild []
Hours Orthosis Worn: Sit Stand	Hours Orthosis Worn: Sit Stand	Hours Orthosis Worn: Sit Stand
Deflated: Today ____ Weekly ____	Deflated: Today ____ Weekly ____	Deflated: Today ____ Weekly ____
Inflated: Today ____ ____ Weekly ____ ____	Inflated: Today ____ ____ Weekly ____ ____	Today ____ ____ Weekly ____ ____
By: Date	By: Date:	By: Date

THERAPIST

STATUS BEFORE FITTING

Customary Body Position - Hours Each: Bed ___ Chair ___ Stand ___ Walk ___

Type of Therapy Program: Bedside Only [] Tilt Table ____° Standing []
Ambulating Assisted [] Ambulating Unassisted []
Other: _____

Range of Motion,
Legs: Right: Hip _____° Knee _____° Ankle _____°
Left: Hip _____° Knee _____° Ankle _____°

Circumference of
Limbs (largest point) Thighs _____ inches Calves _____ inches

Overall Muscle Tone: Flaccid [] Spastic: Severe [] Moderate [] Mild []

THERAPIST OR ORTHOTIST

INITIAL FIT EXPERIENCE

Fitting: OK Without Adjustment []
After Adjustment of: _____
Satisfactory [] Unsatisfactory []

Date First Fitted: _____
Therapist Time
Spent Adjust. ____ min.

Inflation Supine []
Position: Sitting [] Other: _____

Comfort: Immediately Comfortable [] Increasingly Confortable After _____ min.

		Stable	Unstable		Stable	Unstable	
Standing Stability	Trunk:	[]	[]	Hip:	[]	[]	[] Did Not Stand
	Knee:	[]	[]	Ankle:	[]	[]	

		Sitting	Standing
Time Orthosis Worn (Approx.):	Deflated	_____ min.	
	Inflated	_____ min.	Inflated _____ min.

Walking: Time _____ min. distance _____ yds. [] Did Not Walk

CLINIC TEAM

CONCLUSIONS ABOUT THIS PATIENT AND ORTHOSIS

Patient's Attitudes: _____

Special Advantages
or Problems: _____

Patient's Function Compared
to Other Orthosis: _____

Patient's
Acceptance: _____

Team Recommends Orthosis for This
Patient: Yes [] No []
Comment: _____

Expected Eventual
Functional Level _____

Expected Uses/Activities _____

Is the Orthosis Practical in Hospital for Patients of this Type? Yes [] No []
Is the Orthosis Practical at Home for Patients of this Type? Yes [] No []

Date: _____ 19 Team Leader or Recorder: _____

THERAPIST

PATIENT PERFORMANCE SUMMARY

Fitting: Satisfactory [] Adjustment Needed: _____
Unsatisfactory []

Approximate Total Therapist Time Spent: _____ hrs.

Inflation Position Preferred: Supine [] Sitting [] Other: _____

Number of Positions Tried _____

Inflation Problems: None [] Problem: _____ Due to: _____

Respiration While Standing: Not Changed [] Inhibited [] Improved [] Comment: _____

Standing Stability	Stable	Unstable		Stable	Unstable
Trunk:	[]	[]	Knee:	[]	[]
Hip:	[]	[]	Ankle:	[]	[]

[] Did Not Stand

Was Refitting and Adjustment Done to Correct Instability: No []
Yes - Explain: _____

Wearing Pattern:
Typical Times: 1. _____ 2. _____ 3. _____
Preferred: Inflated [] Deflated [] Inflated [] Deflated [] Inflated [] Deflated []

Activities: PT Only [] Other Therapies [] Independent Mobility - Via Walking [] Sitting []

Social Activities _____ Other: _____

Walking Aids Used: Crutches [] Walker [] Other _____

Gait Pattern: Drag to [] Swing to [] Swing through []

Stair Climbing: Not Tried [] Unable [] Can Do With Help [] Can Do Independently []

Climbing Method: _____

Training Time: ____ Sessions of _____ minutes each

Main Uses of Orthosis: _____

Recovery from Fall: Independent [] With Assistance [] Unable [] Not Tried []

Method: _____

Compressor: Probability: OK []
Reliability: OK [] Problems: _____

Donning Orthosis: Independent [] Minor Assistance [] Major Assistance [] Time Needed _____ min.

Doffing Orthosis: Independent [] Minor Assistance [] Major Assistance [] Time Needed _____ min.

Donning Clothing Over Orthosis: Independent [] Not Possible [] With Assistance []

Is Wearing Clothes Over Orthosis Practical: Yes [] No - Explain: _____

Transfer: Sitting to Standing: Independent [] Dependent [] Train Time ____ Sess. ___ min.
Standing to Sitting: Independent [] Dependent [] Train Time ____ Sess. ___ min.
Needs to Use Parallel Bars: []
Needs to Use Other Aids - Explain: _____

Will Patient be Likely to Use Orthosis Independently: Yes []
No - Explain: _____

Therapist Initials:____
Typed Name:

AGENDA

ORIENTATION SESSION

EVALUATION OF THE ORTHO-WALK PNEUMATIC ORTHOSIS

SUBCOMMITTEE ON EVALUATION
COMMITTEE ON PROSTHETICS RESEARCH AND DEVELOPMENT
NATIONAL ACADEMY OF SCIENCES

New York, New York
July 1-3, 1974

		Hartford Room Statler Hilton Hotel 7th Ave. and 33rd St. New York, New York
Monday **July 1, 1974**		
9:00 a.m.	Welcome and Introductions	Michael J. Quigley
	Purpose of the Evaluation	E. E. Harris
	Description of the "Ortho-Walk" Orthosis	Nancy Hivry
	Experience with "Ortho-Walk" Orthosis at Bird S. Coler Hospital	Maurycy Silber
10:30 a.m.	C O F F E E	
	Experience with the "Ortho-Walk" Orthosis at the Institute of Rehabilitation Medicine	Heiner Sell
	Measurements, Fitting, and Training	Nancy Hivry Margaret McGarrity
11:30 a.m.	L U N C H	
1:00 p.m.	Evaluation Structure and Timetable	Michael J. Quigley
	Evaluation Protocol	E. E. Harris
	Panel Discussion	
3:30 p.m.	Final Remarks	
Tuesday **July 2, 1974**		**Bird S. Coler Hospital** **Roosevelt Island**
9:00 a.m.	Orthotist and Therapist Training in Measurement, Fitting, and Therapy	
Wednesday **July 3, 1974**		**Bird S. Coler Hospital** **Roosevelt Island**
9:00 a.m. to 12:00 noon	Orthotist and Therapist Training	

PARTICIPATING CENTERS

ORIENTATION SESSION
EVALUATION OF THE ORTHO-WALK PNEUMATIC ORTHOSIS

SUBCOMMITTEE ON EVALUATION
COMMITTEE ON PROSTHETICS RESEARCH AND DEVELOPMENT
NATIONAL ACADEMY OF SCIENCES

NORTHWESTERN UNIVERSITY MEDICAL SCHOOL

Bupend Agrawal, M.D.
Paul R. Meyer, Jr., M.D.
Joel Rosen, M.D.
Steven R. Huber, R.P.T.
David Thullen, C.O.

CRAIG REHABILITATION HOSPITAL

Harry R. Hahn, M.D.
Alton A. Scott, C.P.O.
Joan Polack, R.P.T.

UNIVERSITY OF MIAMI

Jerry E. Enis, M.D.
William F. Sinclair, C.P.O.
Robin Smith, R.P.T.

VETERANS ADMINISTRATION HOSPITAL, MIAMI

Jorge D. Jacobi, M.D.
Evelyn Carrasquillo, R.P.T.
David N. Dupree, C.P.

VETERANS ADMINISTRATION HOSPITAL, RICHMOND

Charles R. Lamb, Jr., M.D.
Daniel Kahsar, R.P.T.
Hallie C. Ratliffe, Orthotist

VETERANS ADMINISTRATION HOSPITAL, HINES, ILL

David Stern, M.D.
Helaine Hull, R.P.T.
G. Wilbur Pearson, Orthotist

VETERANS ADMINISTRATION HOSPITAL, PALO ALTO

Inder Perkash, M.D.
Deborah Wilson, P.T.
Maurice A. LeBlanc, C.P.

AGENDA

SUBCOMMITTEE ON EVALUATION
COMMITTEE ON PROSTHETICS RESEARCH AND DEVELOPMENT
NATIONAL ACADEMY OF SCIENCES

INTERIM MEETING

EVALUATION OF THE ORTHO-WALK PNEUMATIC ORTHOSIS
Miami Beach, Florida

Sunday December 15, 1974		Westward IV Room Americana Hotel
4:30 p.m.	Welcome and Introductions	Frank W. Clippinger, Jr., Chairman
	Progress Reports	
	Miami VA SCI Service	Evelyn Carrasquillo Jorge D. Jacobi Betsy Powers
	Richmond VA Hospital	Daniel Kahsar
	Hines VA Hospital	G. Wilbur Pearson
	Palo Alto VA Hospital	Inder Perkash
	University of Miami	Jerry E. Enis William F. Sinclair Robin Smith
	Rehab. Inst. of Chicago- Northwestern University	B. Agrawal
	Craig Rehab. Institute	Alton A. Scott
6:30 p.m.	BREAK	
	Further Experiences at Coler Hospital	Maurycy Silber
	Further Experiences at the Institute of Rehabilitation Medicine	Heiner Sell
	Problem Areas a) Fittings b) Evaluation Structure	Michael J. Quigley
	Developer's Comments	Frederick J. Seufert
	Discussion	
7:30 p.m.	Date of Next Meeting	

SUBCOMMITTEE ON EVALUATION
COMMITTEE ON PROSTHETICS RESEARCH AND DEVELOPMENT
NATIONAL ACADEMY OF SCIENCES

REPORT

INTERIM MEETING OF PARTICIPANTS IN THE EVALUATION OF THE ORTHO-WALK PNEUMATIC ORTHOSIS

Westward IV Room, Americana Hotel
Miami Beach, Florida

Sunday, December 15, 1974
4:30 p.m. - 7:30 p.m.

PARTICIPANTS

Chairman	Frank W. Clippinger, Jr.
Representatives of Evaluation Centers	
Miami VA SCI Service	Evelyn Carrasquillo
	Jorge D. Jacobi
	Betsy Powers
Richmond VA SCI Service	Daniel Kahsar
Hines VA SCI Service	G. Wilbur Pearson
Palo Alto VA SCI Service	Inder Perkash
University of Miami	Jerry E. Enis
	Robin Smith
Northwestern University - RIC	B. Agrawal
Craig Rehabilitation Institute	Alton A. Scott
Others Involved	
Bird S. Coler Hospital	Maurycy Silber
Institute of Rehabilitation Medicine	Heiner Sell
CPRD Committee Members	Frank W. Clippinger, Jr.
	Douglas A. Hobson
	Colin A. McLaurin
CPRD Staff	E. E. Harris
	Michael J. Quigley
	G. E. Sharples
	A. Bennett Wilson, Jr.

PREFACE

The Ortho-Walk Pneumatic Orthosis has been undergoing an evaluation by the Committee on Prosthetics Research and Development (CPRD) of the National Research Council, National Academy of Sciences since July 1, 1974. The evaluation was requested by the Veterans Administration (VA) to determine the effectiveness of this orthosis for VA and civilian patients.

Four VA Spinal-Cord Injury (SCI) Services and three private rehabilitation hospitals are participating in the study. A clinic team consisting of a physician, therapist, and orthotist from each center was oriented in New York, July 1-2, and requested to fit up to five paraplegic patients in their hospitals with the orthosis, for a maximum of 35 patients. A patient protocol was decided upon and evaluation forms were distributed for each patient. The progress of the evaluation is being monitored by the staff of CPRD.

The interim meeting was scheduled to review the progress to date and make plans for an orderly termination of the evaluation.

Miami VA-SCI Service

Jorge Jacobi, M.D. and Betsy Powers, therapist, reported their results with five patients. A sixth patient was fitted but rejected the suit very early in the program. In addition to the requested evaluation data, Dr. Jacobi had done blood volume and pulmonary function studies. His initial findings indicated that the pneumatic orthosis increased blood flow to the kidneys, which is a definite physiological benefit with spinal-cord-injury patients.

Ms. Powers recounted the results of therapy with the patients. Four patients were discharged and using the orthosis at home. The estimate of home use ranged from a few hours a week to a few hours a day, depending on the patient.

Two of the patients stated that they felt relief from low-back pain while wearing the orthosis, but after doffing it the pain temporarily was worse than it was originally.

A fifth patient had only been in the program two weeks so no results were reported on him.

A discussion ensued concerning using 36 psi in the tubes of the suit instead of 32 psi, as recommended by the developer. Both the Miami VA and Dr. Silber from Bird S. Coler hospital stated that they used the increased pressure to alleviate problems involving tube bending. Mr. Frederick Seufert, President of ILC Dover, said that the tubes will burst at 65 - 100 psi, and each tube is factory tested up to 65 psi, but it is still not a recommended practice to inflate the tubes more than 32 psi.

McGuire VA-SCI Service

Daniel Kahsar stated that five patients had been through the program. One of the patients, a T_{12} paraplegic with a 20-year-old injury, rejected the suit early in the program. The patient had previously tried conventional orthoses but still preferred the wheelchair. The pneumatic orthosis was used on another patient.

Mr. Kahsar stated that his three active patients can don the suit independently, but it is a long (10 minutes) and exhausting process. He also stressed the need for a miniaturized air supply.

One of the patients who completed the evaluation was independent in donning and doffing, wheelchair to standing transfers, mat to standing transfers, donning clothing over the suit, and ambulation with a walker. Standby assistance was needed when Lofstrand crutches were used.

Mr. Seufert stated that there is a possibility of containing the air supply in the crutch tubing. ILC Dover and Thiokol Corp., are working on this concept at this time.

Mr. Kahsar estimated that he will have completed a three-month follow-up on all patients by March 1975.

Hines VA-SCI Service

Wilbur Pearson, the orthotist from Hines, stated that only one patient had been in their program to date. The patient was a T_6 paraplegic injured in 1953. He was six feet two inches tall, which is out of the recommended size range for the Ortho-Walk.

Mr. Pearson stated that two orthoses had been received the previous week (December 6) and these patients have begun the program. Another suit was ordered on December 1, 1974 and that patient will begin training as soon as the suit is received.

Palo Alto VA SCI Service

Inder Perkash, M.D., stated that five patients had been in the evaluation program at Palo Alto. None of the patients had recent injuries. The length of time since their injuries ranged from two to six years. Three of the patients had lesions at the T_{10} level, one at T_6 and one at T_8.

The only mechanical problem encountered was a broken zipper on one of the orthoses. Due to a postsurgical complication on one of his patients, Dr. Perkash stated that in the future, patients having bladder or neck surgery should wait three weeks postoperative before using the pneumatic orthosis.

He also mentioned problems with thin patients having too much room in the abdominal portion of the suit, and therefore having excessive pressure on the prominences of the pelvis. The use of padding apparently relieved the problem.

The problem of the donning process came up again. The two patients that had the best results in the Ortho-Walk still complained that they spent too much time donning the suit.

All patients had previously used conventional metal orthoses. One patient used the "stand-alone," a device that allows stable hands, free standing, and preferred it to the pneumatic orthosis.

The estimated date of completion of the follow-up on all patients was March.

University of Miami

Dr. Jerry Enis said that there had been three patients in the evaluation, 2 acute and one old injury.

One patient was a beautiful young lady with a T_1 injury who worked for the hospital. Although she was strong, active, and well motivated, the suit would buckle and her legs would spread apart farther and farther as she walked. A four-tube suit was fitted to her by an ILC Dover representative but similar problems were encountered. The patient rejected the suit due to these problems.

Another patient, with a T_{12} injury had hypertrophic bone formations at the hip which caused trunk balance problems. Despite the excessive energy needed to ambulate he used the orthosis daily in therapy.

Dr. Enis stressed the problems encountered by private hospitals when they attempt to admit patients for training only, as was the case during the evaluation. He also said that the amount of therapist time needed was excessive.

Mr. Robin Smith gave an excellent slide presentation clearly demonstrating the progress of each patient. He stated that one of the problems has been with the medial leg zippers tearing open while the patient is standing.

The estimated completion date for the evaluation at this center is May 1, 1975, however, some data will be available on five patients by March 1975.

Rehabilitation Institute of Chicago - Northwestern University

Dr. Agrawal stated that five patients were in the program. One patient rejected the orthosis early in the evaluation, one was a household ambulator in the orthosis, two are still undergoing training and one had not started training.

The estimated completion date at that center is in March 1975.

Craig Rehabilitation Institute

Mr. Alton Scott related the experience of his team in Denver. Four patients had been fitted with the pneumatic orthosis. Two of them had previously used Craig-Scott knee-ankle-foot orthoses (KAFO's). The remaining two patients were new and were fitted simultaneously with the pneumatic orthosis and the Craig-Scott KAFO's.

The only mechanical problems were leakage of air, which occurred twice. The suits were returned to the manufacturer, repaired and sent back after a long delay. One of the patients was discharged and left the Denver area before his suit was returned.

The patients stated that they liked the solid ankle and easy donning that the Craig-Scott KAFO's provided. The hips are left free in the Craig-Scott design, hip motion is stopped in the Ortho-Walk. The patients enjoyed the lightness of the Ortho-Walk but felt the other factors, especially the donning problem, outweighed this advantage.

Mr. Scott mentioned that the amount of time a therapist needs to train a patient was difficult to justify in a private rehabilitation hospital.

Dr. Maurycy Silber's Comments

Dr. Silber said that he agreed by and large with the findings of the group. He had recently returned from a visit to Israel where he fitted a number of paraplegic veterans with the pneumatic orthosis and was extremely successful. He underscored Dr. Jacobi's work, stating that the major benefit of the orthosis is physiological.

Dr. Heiner Sell's Comments

Dr. Sell agreed with the findings of the group and went on to state the results of a research project he and his staff had completed. The results are published in the Institute of Rehabilitation Medicine's publication, "Pneumatic Orthoses for Paraplegics: Functional Evaluation and Prescription Considerations," by Ragnarsson, Sell, McGarrity, and Ofir.

The following statements are from the abstract of the report:

"The purposes of the study were to establish whether pneumatic orthoses could be used by paraplegic patients for effective ambulation, whether these devices presented any advantages or disadvantages over conventional orthoses and how their use would affect the expected level of rehabilitation and independence .... Reduced tendency for orthostatic hypotension, availability, light weight and better endurance make the pneumatic orthosis especially suitable for early ambulation training, but several mechanical problems, mainly its inflation with motorized and heavy compressor units, limit its usefulness for community ambulation."

Dr. Sell mentioned that he had used plastic ankle-foot orthoses to stabilize the ankles of at least one of his patients.

CPRD Comments

Michael Quigley stated that the major problem had been delivery delays. Some of the delays were due to postal problems, others due to the need to wait for a new VA purchase order. Hardly anyone received shoes on time and when they did, the patient was either gone, had used a different pair, or didn't fit in the shoes. Instructions were given to ILC Dover not to fill any more back orders on shoes due to the aforementioned problems.

Most of the patients in the evaluation were outpatients, Mr. Quigley stated, which is a violation of the original protocol. However, patient recruitment was extremely difficult during the first few months of the evaluation so the protocol was modified.

All clinics were requested to make sure the forms were complete in all categories, as this will be the only record of the patient that will be used. All completed forms should be ready to be sent to CPRD in late February.

No more patients are to be recruited for the CPRD/VA evaluation, as the quota of 35 patients has been reached. Until the final meeting, the clinics should concentrate on completing the training for all patients presently involved.

Developer's Comments

Frederick Seufert, President of ILC Dover, stated that the company had a policy of sending out both new orders and repairs forty-eight hours after they are received. He said that they had many problems with their original shoe supplier, and the supplier has since been changed.

Mr. Seufert explained the indications for a new four-tube suit that may become standard for patients over 155 pounds or over six feet tall. He said that some of the problems encountered in the evaluation may be solved by use of the four-tube suit.

A new instruction manual is being written, based on the original manual prepared for the evaluation. The staff at Bird S. Coler Hospital have edited the manual and are working with the ILC Dover Company to complete it. Dr. Silber and Mr. Seufert stated that the manual would be forwarded to CPRD for distribution to the evaluation centers as soon as possible. The evaluation participants could then review the content of the manual by the time of the final meeting.

Date of Final Meeting

The date of Monday, March 17, was tentatively set for the final meeting. Denver, Colorado may be the location of the meeting, which will afford the participants a chance to visit both Craig Rehabilitation Hospital and the scenic surroundings.

Chairman's Summary

Dr. Frank Clippinger summarized the proceedings. He said that the Ortho-Walk Pneumatic Orthosis does what the developer claims it will do, providing the correct size is fitted properly on a patient who has sufficient strength and few medical complications and receives proper training in the use of the suit. The majority of problems were traced to medical complications, and patients who were out of the range of the standard sizes.

ORTHO-WALK EVALUATION
INTERIM MEETING

Progress Report*

EVALUATION CENTER	PATIENTS NOT ACTIVE	PATIENTS ACTIVE	TOTAL PATIENTS	SUITS ORDERED	SUITS RECEIVED	SUITS REJECTED	TOTAL SUITS TO DATE
MIAMI VA	1	5	6	6	6	1	6
RICHMOND VA	3	2	5	5	4	1	4
HINES VA	1	4	5	5	5	1	5
PALO ALTO VA	2	3	5	3	3	2	3
UNIVERSITY OF MIAMI	2	3	5	5	5	1	5
NORTHWESTERN UNIVERSITY	2	3	5	5	5	1	5
CRAIG REHAB. HOSPITAL	4	0	4	4	4	4	4
TOTAL	15	20	35	33	32	11	32
COLER HOSPITAL	1	4	5	3	3	0	3

*All figures taken from progress reports submitted by the participants of the Interim Meeting.

APPENDIX E

AGENDA

FINAL MEETING

EVALUATION OF THE ORTHO-WALK PNEUMATIC ORTHOSIS

SUBCOMMITTEE ON EVALUATION
COMMITTEE ON PROSTHETICS RESEARCH AND DEVELOPMENT
NATIONAL ACADEMY OF SCIENCES

March 17-18, 1975
Denver, Colorado

Monday March 17, 1975		Craig Rehabilitation Hospital 3425 South Clarkson Englewood, Colorado
8:30 a.m.	Welcome	A. Bennett Wilson, Jr., Chairman
	Organization of the Meeting	Michael J. Quigley
	Needs of the Veterans Administration	Madison Lyles, Jr.
	Final Report of the Participants	
	Miami VA-SCI Service	Michael Dunn Betsy Powers
	Richmond VA-SCI Service	Daniel Kahsar
	Hines VA-SCI Service	Helaine Hull G. Wilbur Pearson David Stern
	Palo Alto VA-SCI Service	Maurice A. LeBlanc Inder Perkash Deborah Wilson
10:00 a.m.	BREAK	
	University of Miami	Jerry E. Enis and Robin Smith
	Rehabilitation Institute of Chicago-Northwestern University	B. Agrawal Steven R. Huber David Thullen
	Craig Rehabilitation Hospital	Harry R. Hahn Joan Polack Alton A. Scott
	Report from other Evaluation Programs	
	Institute of Rehabilitation Medicine Bird S. Coler Hospital University of Washington	Heiner Sell Maurycy Silber
12:30 p.m.	LUNCH	
1:30 p.m.	Summary of Results	Michael J. Quigley
1:45 p.m	Plenary Session	A. Bennett Wilson, Jr.
2:00 p.m.	Group Sessions to Make Recommendations	

Tuesday
March 18, 1975

8:30 a.m.	Recommendations of Group I: Medicine	Jerry E. Enis
	Recommendations of Group II: Therapy	Robin Smith
	Recommendations of Group III: Orthotics	David Dupree
	Discussion and Critique of Recommendations	
	End of Evaluation Meeting	
10:00 a.m.	Craig Rehabilitation Hospital Philosophy of Treatment	Harry R. Hahn
10:30 a.m.	Tour	
11:30 a.m.	Movie "Changes" (30 minutes)	

WORKSHOP SESSIONS

The leader of each group is to guide the discussions to produce recommendations from the general outline. The recorder of each group is to assist by putting down on paper the results of the discussions for presentation Tuesday morning and for the published report of the meeting.

GROUP I: Medicine

Leader: Jerry E. Enis

Recorder: A. Bennett Wilson, Jr.

Participants: B. Agrawal, Michael Dunn, Harry Hahn, Inder Perkash, Heiner Sell, Maurycy Silber, and David Stern.

A. Prescription Rationale

Please consider each area and state indications and contra-indications when possible.

1. Age
2. Height
3. Weight
4. Body Build
5. Occupation
6. Mobility Needs
7. Previous Orthotic Experience
8. Level of Wheelchair Independence
9. Etiology
10. Lesion Level
11. Bowel and Bladder Conditions
12. Cardiovascular Conditions
13. Respiratory Conditions
14. Spasticity
15. Other Concurrent Pathologies
16. Attitude

B. Obtain a consensus in the following areas and state specific recommendations when possible.

1. Practicality for Therapeutic Use
2. Practicality for Home Ambulation
3. Practicality for Community Ambulation
4. Necessity for Therapy
5. Cost Effectiveness

C. Please list the specific advantages and disadvantages of the Ortho-Walk, considering physiological, mechanical, and social aspects.

D. List recommendations for future studies or designs in pneumatic orthotics.

E. Do you recommend that the Ortho-Walk Type B Pneumatic Orthosis be provided to patients under care of the Veterans Administration or by other third party payees, as long as these parties are aware of the recommendations put forth by the participants of this evaluation?

GROUP II: Therapy

Leader: Robin Smith

Recorder: G. E. Sharples

Participants: Helaine Hull, Steve Huber, Daniel Kahsar, Madison Lyles, Joan Polack, Betsy Powers, and Deborah Wilson.

A. Prescription Recommendations

Establish specific indications, contraindications or opinions about the use of the Ortho-Walk for the following categories:

1. Age
2. Height
3. Weight
4. Body Build (strength)
5. Occupation
6. Mobility Needs
7. Previous Orthotic Experience
8. Level of Wheelchair Independence
9. Spasticity
10. Lesion Level
11. Phase of Recovery (acute, chronic, etc.)
12. Range of Motion
13. Attitude

B. Obtain a consensus in the following areas and state specific recommendations when possible.

1. Practicality for Therapeutic Use
2. Practicality for Home Ambulation
3. Practicality for Community Ambulation
4. Therapy Program
   - (a) Inpatient or Outpatient
   - (b) Length of Program
   - (c) Gait Patterns
   - (d) Inflation, Deflation Techniques
   - (e) Walking Aids
   - (f) Stair Climbing
   - (g) Recovery
   - (h) Clothes
   - (i) Transfers
   - (j) Length of Time in Suit (inflated, deflated)
   - (k) Cost Effectiveness

C. List the specific advantages and disadvantages of the Ortho-Walk and make recommendations for future design modifications.

D. Do you recommend that the Ortho-Walk Type B Pneumatic Orthosis be provided to patients under care of the Veterans Administration or by other third party payees, as long as these parties are aware of the recommendations put forth by the participants of this evaluation?

GROUP III: Orthotics

Leader: Maurice A. LeBlanc

Recorder: David Dupree

Participants: Wilbur Pearson, Alton Scott, and David Thullen.

A. Prescription Rationale

Please consider each area and state indications, contraindications or opinions.

1. Age
2. Height
3. Weight
4. Body Build (strength)
5. Occupation
6. Mobility Needs
7. Previous Orthotic Experience
8. Contractures

B. Describe the advantages, disadvantages or problems with each of the following techniques or components.

1. Measurement
2. Size Range
3. Initial Fitting
4. Adjustment Straps
5. Leg Zippers
6. Waist Zipper
7. Snaps
8. Toe Lifter Straps (ankle control)
9. Pneumatic Beams
10. Inflation Valve
11. Deflation Hose and Valve
12. AC Compressor
13. DC Compressor
14. Orthopedic Shoes
15. Donning Procedure
16. Doffing Procedure

C. Make recommendations for future design modifications of the orthosis.

D. Do you recommend that the Ortho-Walk Type B Pneumatic Orthosis be provided to patients under care of the Veterans Administration or by other third party payees, as long as these parties are aware of the recommendations put forth by the participants of this evaluation?

GENERAL PARTICIPANTS

EVALUATION OF THE ORTHO-WALK PNEUMATIC ORTHOSIS

AGRAWAL, Bupend, M.D., Rehabilitation Institute of Chicago, 345 Superior Street, Chicago, Illinois 60611

APPOLDT, Francis A., Veterans Administration Prosthetics Center, 252 Seventh Avenue, New York, New York 10001

BAGGETT, Bonnie, ILC Dover, 350 Pear Street, Dover, Delaware 19901

BAILEY, Melvin, Bird S. Coler Hospital, Roosevelt Island, New York, New York 10017

CARRASQUILLO, Evelyn, R.P.T., Veterans Administration Hospital, 1201 Northwest 16th Street, Miami, Florida 33125

CLIPPINGER, Frank W., Jr., M.D., Duke University Medical Center, Durham, North Carolina 27710

DUNN, Michael, Ph.D., Veterans Administration Hospital, 1201 Northwest 16th Street, Miami, Florida 33125

DUPREE, David N., C.P., Veterans Administration Hospital, 1201 Northwest 16th Street, Miami, Florida 33125

ENIS, Jerry E., M.D., University of Miami School of Medicine, P. O. Box 875, Biscayne Annex, Miami, Florida 33152

HAHN, Harry R., M.D., Craig Rehabilitation Hospital, 3425 South Clarkson, Englewood, Colorado 80110

HARRIS, E. E., M.R.C.S., Committee on Prosthetics Research and Development, National Academy of Sciences, 2101 Constitution Avenue, N.W., Washington, D.C. 20418

HIVRY, Nancy, Bird S. Coler Hospital, Roosevelt Island, New York, New York 10017

HOBSON, Douglas A., P. Eng., Crippled Children's Hospital School, 1248 La Paloma Street, Memphis, Tennessee 38111

HUBER, Steven R., R.P.T., Rehabilitation Institute of Chicago, 345 Superior Street, Chicago, Illinois 60611

HULL, Helaine, R.P.T., Veterans Administration Edward Hines, Jr., Hospital, Hines, Illinois 60141

JACOBI, Jorge D., M.D., Veterans Administration Hospital, 1201 Northwest 16th Street, Miami, Florida 33125

KAHSAR, Daniel, R.P.T., Veterans Administration Hospital, 1201 Broad Rock Road, Richmond, Virginia 23249

KAY, Hector W., Committee on Prosthetics Research and Development, National Academy of Sciences, 2101 Constitution Avenue, N.W., Washington, D.C. 20418

LAMB, Charles R., Jr., M.D., Veterans Administration Hospital, 1201 Broad Rock Road, Richmond, Virginia 23249

LeBLANC, Maurice A., Children's Hospital at Stanford, 520 Willow Road, Palo Alto, California 94304

LYLES, Madison, Jr., Veterans Administration Prosthetics Center, 252 Seventh Avenue, New York, New York 10001

McGARRITY, Margaret, R.P.T., Institute of Rehabilitation Medicine, NYU Medical Center, 400 East 34th Street, New York, New York 10016

McLAURIN, Colin A., D.Sc., Ontario Crippled Children's Centre, 350 Rumsey Road, Toronto, Ontario, Canada M4G 1R8

MEYER, Paul R., Jr., M.D., 233 E. Erie Street, Chicago, Illinois 60611

NELSON, Peter J., Committee on Prosthetics Research and Development, National Academy of Sciences, 2101 Constitution Avenue, N.W., Washington, D.C. 20418

OFIR, Reuven, P.T., Institute of Rehabilitation Medicine, NYU Medical Center, 400 East 34th Street, New York, New York 10016

PEARSON, G. Wilbur, Orthotist, Veterans Administration Edward Hines, Jr., Hospital, Hines, Illinois 60141

PERKASH, Inder, M.D., Veterans Administration Hospital, 3801 Miranda Avenue, Palo Alto, California 94304

PIRRELLO, Thomas, Jr., C.P.O., Veterans Administration Prosthetics Center, 252 Seventh Avenue, New York, New York 10001

POLACK, Joan, R.P.T., Craig Rehabilitation Hospital, 3425 South Clarkson, Englewood, Colorado 80110

POWERS, Betsy, C.C.T., Veterans Administration Hospital, 1201 Northwest 16th Street, Miami, Florida 33125

QUIGLEY, Michael J., C.P.O., Committee on Prosthetics Research and Development, National Academy of Sciences, 2101 Constitution Avenue, N.W., Washington, D.C. 20418

RATLIFFE, Hallie C., Orthotist, Veterans Administration Hospital, 1201 Broad Rock Road, Richmond, Virginia 23249

ROSEN, Joel, M.D., Rehabilitation Institute of Chicago, 345 Superior Street, Chicago, Illinois 60611

SCOTT, Alton A., C.P.O., Craig Rehabilitation Hospital, 3425 South Clarkson, Englewood, Colorado 80110

SELL, Heiner, M.D., Institute of Rehabilitation Medicine, NYU Medical Center, 400 East 34th Street, New York, New York 10016

SEUFERT, Frederick J., ILC Dover, 350 Pear Street, Dover, Delaware 19901

SHARPLES, G. E., Ph.D., Committee on Prosthetics Research and Development, National Academy of Sciences, 2101 Constitution Avenue, N.W., Washington, D.C. 20418

SILBER, Maurycy, M.D., Bird S. Coler Hospital, Roosevelt Island, New York, New York 10017

SINCLAIR, William F., C.P.O., University of Miami School of Medicine, P. O. Box 875, Biscayne Annex, Miami, Florida 33152

SKURNIK, Deborah, P.T., Rehabilitation Institute of Montreal, 6300 Darlington Avenue, Montreal, Quebec, Canada H3S 2J4

SMITH, Robin, R.P.T., University of Miami School of Medicine, P. O. Box 875 Biscayne Annex, Miami, Florida 33152

STAROS, Anthony, Veterans Administration Prosthetics Center, 252 Seventh Avenue, New York, New York 10001

STERN, David, M.D., Veterans Administration Edward Hines, Jr., Hospital, Hines, Illinois 60141

THRANHARDT, Howard R., C.P., J. E. Hanger, Inc., 947 Juniper Street, N.E., Atlanta, Georgia 30309

THULLEN, David, C.O., Northwestern University, 345 Superior Street, Chicago, Illinois 60611

WILSON, A. Bennett, Jr., Committee on Prosthetics Research and Development, National Academy of Sciences, 2101 Constitution Avenue, N.W., Washington, D.C. 20418

WILSON, Deborah, P.T., Veterans Administration Hospital, 3801 Miranda Avenue, Palo Alto, California 94304

WRIGHT, Donald W., Veterans Administration Prosthetics Center, 252 Seventh Avenue, New York, New York 10001