A Survey of Eight Wearers of the Veterans Administration Prosthetics Center Patellar Tendon-Bearing Brace

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A SUMMARY

I. Introduction

Bracing to relieve weightbearing stresses of the lower extremity has been achieved by loading the brace at the level of the pelvis, with the wearer essentially "sitting" on the proximal portion of the brace. Weight is then transmitted to the ground through an exoskeleton of sidebars and locked knee. The disadvantages of this type of brace are its bulk and the locked knee. When the pathology is located above the knee such disadvantages may be unavoidable. In the case of certain below-knee lesions, however, a weight-bearing brace which does not extend above the knee is desirable and appears theoretically feasible. Such a brace would be less bulky and would allow unrestricted knee motion and a more natural gait.

In 1958 the Veterans Administration Prosthetics Center (VAPC) designed a below-knee weight-bearing brace to meet the needs of a patient who was unable to bear weight on his foot.[1] This individual had previously been fitted with both a locked-knee ischial-bearing brace and a short leg brace with weight borne on the tibial condyles. He had rejected both of these devices.

The VAPC design is based on current below-knee prosthetic techniques. The primary weight-bearing component is a partial socket of laminated plastic similar to the proximal portion of a patellar tendon-bearing (PTB) below-knee prosthesis. A steel frame is laminated to the socket. Uprights anchored to this frame transmit the patient's weight, through rigid or limited motion ankle joints, to the heel of the shoe and the ground.

Conventional fitting and alignment techniques are used for the uprights, ankle joints and shoe attachment. A SACH heel wedge and a rocker bar are incorporated in the shoe to simulate plantar flexion and provide a more natural rollover from heel to toe.[2] These shoe modifications are designed to minimize the gait deviations imposed by limited ankle motion. The SACH heel wedge is also considered to function as a shock absorber, contributing to a smoother gait.

[1] McIlmurray, William and Greenbaum, Werner, *A Below Knee Weight Bearing Brace*, ORTHOPEDIC AND PROSTHETIC APPLIANCE JOURNAL, June 1958, pp. 81-82.

[2] McIlmurray, William and Greenbaum, Werner, *The Application of SACH Foot Principles to Orthotics*, ORTHOPEDIC AND PROSTHETIC APPLIANCE JOURNAL, December 1959, pp. 37-40.

The Committee on Prosthetics Research and Development (CPRD) in December 1963 selected the VAPC design as a suitable item for evaluation under the Orthotic Evaluation Program to be inaugurated by New York University. The planned evaluation of the VAPC device will cover three phases:

(1) Review and examination of subjects fitted by the VAPC;
(2) Selection, fitting and evaluation of subjects by NYU;
(3) Selection, fitting and evaluation of patients by cooperating field clinics.

This report is confined to the procedures employed and the results obtained in the first stage of the evaluation.

II. Purpose

The primary objective of the review was to determine the value of the experimental device in relation to the conditions for which it had been prescribed. Three possible levels of findings were hypothesized:

(1) The brace made a positive contribution to the amelioration of the condition.
(2) The brace had a stabilizing effect: it neither improved nor aggravated the condition.
(3) The brace had a negative effect: it aggravated the condition.

As a secondary goal, criteria for the prescription of this type of weight-bearing brace were investigated to the extent permitted by the available data.

III. Methodology

The study was conducted by a research group composed of three physicians (one orthopedist and two physiatrists), an orthotist and a physical therapist. The following aspects of brace wear were investigated:

Medical. The group reviewed each patient's history, focusing on pathological status prior to fitting and at the time of the review. Conclusions as to effect on pathology were drawn, based primarily on comparative X-rays. The applicability of the brace to related pathologies also was considered.

Performance Evaluation. Patient-performance during level walking and stair climbing was rated subjectively, with neuromuscular deficit, habit patterns and brace characteristics considered as possible sources of deviations from normal gait.

Wearer Reaction. The braces were rated with regard to comfort and fit, functional characteristics, maintenance requirements and general characteristics. Where applicable, comparisons with previously used devices also were made.

Orthotic. The group investigated the types of braces worn previously, and the subjects' experiences with them. The experimental braces were examined to determine the types of components used, and to identify fabrication and alignment characteristics in relation to pathology.

IV. Sample

From 1958 to November 1963, the VAPC fitted the PTB brace to 22 patients, all of whom had defects of the below-knee weight bearing structures. Eight of the 22 patients participated in the evaluation procedures. The fourteen additional subjects did not participate in the review despite maximum efforts on the part of both NYU and the VA to secure their cooperation. The eight patients reviewed may constitute a select rather than random or representative sample, but this does not invalidate the findings of the review. However, broad generalizations from these findings would hardly be warranted without further study.

TABLE I

DESCRIPTION OF SAMPLE
(N = 8)

Subject	Age	Height	Weight	Pathology	Prior Braces
N.C.	44 y 8 m	5'7"	220	Nonunion, tibia	1. Ischial bearing 2. Short leg with condylar bearing
D.D.	46 y 7 m	6'0"	182	Traumatic and surgical ankle joint changes	1. Short leg, weight-bearing 2. Short leg, standard
R.M.	34 y 2 m	6'1"	180	Same	1. Ischial bearing
D.M.	33 y 11 m	5'6"	185	Malunion and joint changes	1. Ischial bearing with Hessing anklet
W.N.	44 y 10 m	5'10½"	192	Traumatic and surgical joint changes	None
A.R.	39 y 10 m	6'0"	155	Traumatic joint changes	None
A.S.	39 y 6 m	5'9½"	166	Absent os calcis	1. Short leg brace 2. Ischial bearing
W.T.	47 y 7 m	6'4"	153	Traumatic and surgical joint changes	1. Short leg brace

V. Results

A. *Medical.* The eight subjects reviewed exhibited clinical symptoms of skeletal and/or soft tissue intolerance to the stresses of weight bearing. The medical findings related to wear of the experimental brace are summarized below for each of the eight patients:

Subject N.C. The X-ray evidence indicated that the experimental brace, worn during the period 1958-1964, apparently produced a slight improvement in the patient's condition. No increase in the deformity was detectable, and although the tibial nonunion persisted, it was somewhat less marked.

Subject D.D. This patient's pathology apparently stabilized during the 5½ year period of experimental brace wear. No progression of bony pathology could be determined by comparison of reports of X-rays taken some time prior to fitting of the experimental brace and those taken for purposes of this review. The subject's pain had decreased.

Subject R.M. No objective evidence of change in the condition of the os calcis was apparent following 14 months wear of the experimental brace. Nevertheless, the subject's pain on weight bearing had decreased.

Subject D.M. The radiological data demonstrated a definite improvement in the status of the tibial malunion. The condition, which had persisted for nearly three years despite surgery, appeared to have healed during the 17 month period the experimental brace had been worn.

Subject W.N. The comparative X-rays showed no significant changes in condition. There was, however, a reduction in pain during the 5¾ years of experimental brace wear.

Subject A.R. This subject had worn the experimental brace for a period of 4 years 11 months. Initially, there had been marked reduction in pain with stabilization at a tolerable level. More recently, however, pain at the instep and metatarsals had increased, with associated pain in the hip. These

symptoms were in conflict with the stabilized condition indicated by the X-rays. It was not clear, therefore, whether the experimental brace had contributed negatively or positively to the patient's condition.

Subject A.S. This subject was the first patient fitted with this brace design by the VAPC. He had worn the item continuously for 6½ years, with generally beneficial results. No progression of the arthritic process was evident radiographically, and osteoporosis had decreased. The subject's functional capacities had improved.

Subject W.T. Comparison of the patient's condition as reported in the medical history with his current status led to the conclusion that no increase of the bony pathology had occurred. Pain was apparently less. The three years of brace wear had seemingly stabilized the patient's condition.

B. *Performance.*

1. *Level walking:* The eight subjects exhibited a minimum of gait deviations. The only atypical characteristic common to all subjects related to knee motion, which differed from the "normal" cycle of: (1) extension at heel strike followed by flexion to foot-flat; (2) gradual extension from foot-flat through mid-stance, with maximum extension reached just prior to heel-off; (3) terminal flexion immediately following heel-off.

The deviation from normalcy varied in degree with different subjects, but the pattern was uniform. Typically, the knee was flexed at heel-strike, and flexion increased to foot-flat. The knee was then "snapped back," producing abrupt extension immediately after foot-flat, rather than gradual knee extension just before heel-off as in the normal cycle. Terminal knee flexion occurred later than normal and was abrupt. This gait characteristic, which is also typical of below-knee amputees fitted with Patellar Tendon-Bearing prostheses, is attributed to the flexed knee alignment of the device (up to 20°) which prevents complete knee extension.

Shortened stride length, shortened stance time and external rotation of the involved extremities are deviations of gait typically found in situations of limited ankle motion and pain. Even though the experimental brace incorporated rigid or limited motion ankle joints and had been prescribed for conditions of painful weight bearing, these characteristic gait deviations were not present. Apparently the SACH heel wedge and rocker bar application, which simulated plantar flexion of the ankle, had offset the typical effect of a limited motion ankle joint, while alleviation of the pain-producing stress of weight bearing had eliminated this cause of gait deviation.

The four subjects who had previously worn ischial-bearing locked knee braces did not exhibit any carry-over of the stiff kneed gait typical of such devices.

2. *Stair climbing:* Methods of stair ascent and descent varied widely among the eight subjects. The common element in all the variations was the reduction in use of the affected knee. Inability to bring the knee into full extension because of the flexion alignment of the socket was seen as the causative factor in all the variations in technique exhibited.

C. *Wearer Reactions.* Tables III, a-d, present a composite of the patients' ratings.*

* Tables II and IV have been omitted from this summary.

TABLE III

PATIENT REACTIONS TO THE EXPERIMENTAL BRACE
(N = 8)

IIIa—Comfort and Fit

	Responses				
	Excellent	Good	Adequate	Poor	Very Poor
Overall comfort	3	4	1	—	—
Overall comfort after prolonged sitting	1	2	4	1	—
Comfort in knee area after prolonged sitting	3	3	1	1	—
Comfort in weight-bearing area	2	3	2	1	—
Comfort with respect to perspiration	1	2	2	—	3
Comfort with respect to pain*	5	1	1	—	—
Estimation of fit	2	4	2	—	—
Percentage of responses	30.9	34.5	23.6	5.5	5.5

* One additional subject reported no pain with brace wear.

Findings in regard to comfort and fit were generally positive (approximately 65% in Good and Excellent categories.) Six of eight patients had little or no pain in the affected area.

IIIb—Functional Characteristics

	Responses				
	Excellent	Good	Adequate	Poor	Very Poor
Limp	1	4	3	—	—
Impact shock	1	4	3	—	—
Heel-to-toe transition:					
a. as regards smoothness	2	4	1	1	—
b. as regards effort required	2	3	3	—	—
Contribution to security	7	1	—	—	—
Usability (extent of time)	6	2	—	—	—
Percentage of responses	39.6	37.5	20.8	2.1	0

These reactions were emphatically positive (77% in Good to Excellent categories.) Particularly interesting are the ratings accorded security of the brace and the extended periods of time the brace could be worn.

The subjects were also asked to estimate the percentage of body weight borne by the brace during stance phase. Estimates ranged from a maximum of 90 percent to a minimum of 40 to 60 percent.

IIIc—Maintenance and Repair

	Responses				
	Excellent	Good	Adequate	Poor	Very Poor
Durability (frequency of repair):					
a. Socket	3	4	1	—	—
b. Other parts	3	2	2	1	—
Maintenance of cleanliness	3	4	1	—	—
Percentage of responses	37.5	41.7	16.7	4.1	0

As indicated in Table IIIc, the repair and adjustment requirements of the VAPC brace were quite low. One subject required repairs every one to three months, but in all other cases the need arose less frequently.

IIId—General Characteristics

	Responses				
	Excellent	Good	Adequate	Poor	Very Poor
Weight of brace	—	1	4	3	—
Interference with clothing	2	3	—	2	1
Incidence of backache	2	4	—	1	1
Overall value of brace	4	4	—	—	—
Percentage of responses	25.0	37.5	12.5	18.8	6.2

The subjects' opinions concerning the relative merits of their conventional and experimental braces were reported by the patients on the same factors as their evaluations of the experimental braces.

On *Comfort and Fit*, 69.4% reported that the experimental brace was Much Better, and 19.4% that it was Better than the conventional brace.

On *Functional Characteristics*, 71.4% reported Much Better and 11.9% reported that it was Better.

On *Maintenance and Repair* the response was: Much Better, 30%; Better, 40%.

On *General Characteristics* the response was: Much Better, 60.9%; Better, 8.7%.

D. *Orthotic.* The subjects had used the experimental brace design for periods ranging from a minimum of ten months to a maximum of six and one-half years. As shown in Table V, the components incorporated in the eight experimental braces were reasonably uniform. All except the PTB socket are in common use. Four individuals were provided with a small amount of dorsiflexion ankle motion, while the other four had no ankle motion. Custom-made shoes with fillers were worn by five of the subjects to compensate for shortening of the involved extremity.

TABLE V

COMPONENTS OF PTB BRACE
(N = 8)

Subject	Socket	Brace-Shoe Attachments	Ankle Joint		Shoe Modifications	
			Type	R.O.M.	SACH Wedge	Rocker Bar
N.C.	P.T.B.	Solid stirrup	Clevis	7° (D.F.)	Yes	Yes
D.D.	P.T.B.	Split stirrup	Clevis	None	Yes	No
R.M.	P.T.B.	Solid stirrup	Clevis	8° (D.F.)	No	Yes
D.M.	P.T.B.	Foot plate-molded sandal	Solid	None	No	No
W.N.	P.T.B. (modified*)	Solid stirrup	Clevis	6° (D.F.)	Yes	Yes
A.R.	P.T.B.	Solid stirrup	Lap (welded)	None	Yes	Yes
A.S.	P.T.B.	Solid stirrup	Clevis	8° (D.F.)	Yes	Yes
W.T.	P.T.B.	Solid stirrup continuous with upright	Solid	None	No	Yes

* Patellar and femoral condylar extensions missing.

Examination of the braces indicated that, in general, they were well constructed, functionally adequate and quite durable. However, not all of the braces fitted optimally and some deviations from standard orthotic practice were noted. These factors were apparently not of sufficient magitude to affect the adequacy of the brace as a whole critically.

SUMMARY AND CONCLUSIONS

The initial phase in the evaluation of the VAPC brace involved an examination of eight of the 22 patients fitted by the developer during the period 1958-1963.

Three possible levels of findings were hypothesized with respect to the effects of the experimental brace, viz., positive, stabilizing or negative.

The objective evidence obtained (comparative X-rays) indicated definite improvement in the skeletal condition of one subject; two showed slight improvement and five showed no change. The one subject exhibiting definite improvement also reported pain-free ambulation. Six of the remaining seven subjects reported that they still experienced some pain but significantly less than with earlier braces. One subject indicated that pain was recurring after several years of relief.

Insofar as the subject showing definite improvement is concerned, it is conceivable that healing of the tibial malunion might have occurred simply with the passage of time. However, this had not happened in the three year post-trauma and surgery period prior to fitting of the patellar tendon-bearing brace. Hence, wear of the experimental brace must be considered as having contributed to healing. Results with the six subjects who reported relief or decrease of pain and whose X-rays showed slight improvement or no change might also be considered positive. Progression of symptoms and arthritic pathology would usually be expected in such cases as those reviewed. Lack of progression, therefore, may constitute a second-order benefit attributable to reduction in weight-bearing stress. Thus, in seven of the eight cases the outcomes appeared to be positive or at least stabilized. In the case of the one subject who reported recurrence of pain, the outcome of the fitting might be interpreted as equivocal or negative, although there was no objective evidence of deterioration.

Thus the review data indicate that, in general, the brace design under study is an effective method of treatment for below-knee conditions that require unweighting of the limb. Use of this brace is considered to be indicated in situations of structural instability (including nonunion of the tibia), excessive pain on weight bearing, persistent infection or a combination of these factors resulting from trauma and/or surgery of the leg, ankle or foot. In cases of nonunion, use of this item would involve consideration of the extent of instability as well as the location of the fracture, since highly unstable fractures would generally preclude any mobility of the individual. In any event, an intact weight-bearing area below the knee is an essential prerequisite.

The patellar tendon-bearing socket has been used successfully with stirrup attachments (rigid and limited motion ankle joints) and with a foot plate-molded sandal attachment.

In the experimental brace as in prosthetic appliances, the PTB socket is fabricated to fit snugly with pressure applied to the prepatellar tendon and tibial flares with a stabilizing counter-pressure exerted in the popliteal space. The amount of weight taken on the proximal socket is influenced both by the intimacy of fit and by the degree of initial flexion in which the socket is set.

The length of the sidebars can also be varied to control the amount of contact between the foot and the shoe, thus changing the amount of weight taken on the brim. It is noteworthy that the subjects interviewed tended to loosen the strap fasteners on the socket for greater comfort; but by so doing, of course, they reduced the effectiveness of the weight-bearing characteristics of the socket.

Essentially, the orthotist attempts to fit the brace with provision for weight-bearing sufficient to eliminate or significantly relieve pain, and commensurate with the wearer's tolerance of pressure on the prepatellar tendon and tibial flares.

The intimate contact and stability of the socket in the knee area require that during fabrication provision be made for anatomical variations in the ankle and foot. Adequate compensation must be provided for toe-out, tibial bowing and foot malformation. The ankle motion limitations imposed by this type of brace reduce the need to compensate for excessive tibial torsion.

Ambulatory function with the PTB brace approaches the normal. The only significant deviations are related to knee action during stance phase (between heel-contact and mid-stance, and between heel-off and toe-off). In both instances, the deviations appear to be directly related to the flexion alignment of the socket. Variations in stair-climbing techniques also appear to be associated with this alignment factor.

The subjective reactions of the wearers to the brace were generally positive, reaffirming the medical and performance findings.

Since the results of the study to date indicate that the VAPC patellar tendon-bearing brace is an effective device from the medical, orthotic, functional, and wearer-reaction points of view, activation of the second phase of the evaluation program—fitting of subjects by New York University—appears fully warranted.

University of Miami Prosthetics Seminar Scheduled

The University of Miami will present, for the third consecutive year, a three-day seminar on "The Lower Extremity Amputee—Surgery and Prosthetics Management" on December 1-3, 1966 at the Americana Hotel at Miami Beach, Florida.

This seminar will include discussions on preventive and reconstructive surgery in peripheral vascular disease; new concepts in surgery; myoplastic procedures; immediate postoperative fitting; biomechanics of human locomotion; and basic prosthetic principles in the adult and juvenile amputee. Research and new developments will also be discussed.

A limited number of traineeships are available. For application and further information, write to Augusto Sarmiento, M.D., Division of Orthopaedics, Jackson Memorial Hospital, Miami, Florida.