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Evaluation of the Seattle Foot

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Evaluation of the Seattle Foot was the first major evaluation project undertaken by the Rehabilitation Research and Development Evaluation Unit. As a joint project with the Prosthetic and Sensory Aids Service, it not only helped to launch an important new prosthetic foot concept but also set precedents for methods and procedures to evaluate promising prototype devices and to facilitate their commercialization. A great many people contributed to this project. Fred Downs and Edward Nowack organized the service delivery of the Seattle Foot through their 44 Prosthetic Clinics in VAMCs across the nation. The clinic chiefs and the prosthetic contractors gave freely of their time to ensure that evaluation data and comments were obtained and reported. Ernest Burgess and his Prosthetic Research Study staff developed evaluation protocols on which this evaluation was based. Finally, the 486 amputee veteran subjects made the evaluation a credible reality with their thoughtful responses.

BACKGROUND

The Seattle Foot is an artificial foot intended to be attached to a "below-knee (BK)" or an "above-knee (AK)" prosthesis. It was developed by Ernest M. Burgess, M.D., Director of the Prosthetic Research Study at the VAMC in Seattle, Washington under a research project of the Rehabilitation R&D Service, Margaret J. Giannini, M.D., Director. Dr. Burgess was assisted by Donald Poggi, an engineer familiar with contemporary materials technology. The result is a prosthetic foot that employs a plastic keel or leafspring embedded in a cosmetic foam foot. This keel deflects under load, storing the amputee's stance energy and then returns this energy when the amputee steps off his foot giving him a noticeable "push". The action is somewhat like that of the achilles tendon in a normal foot. Amputees involved in Dr. Burgess's project were reported to have improved and quicker gait and increased agility in sport activities.

EVALUATION PROCESS

Evaluation as practiced by the Rehab R&D Evaluation Unit and the Prosthetic Sensory Aids Service follow four distinct steps:

I. *In-house* or *internal evaluation* is done by the developer to determine how well his design meets his original goals. Since a new device almost never works as well as intended the first time, the result of *in-house evaluation* is almost always a change of both goals and design. A new concept may be tried out and redesigned many times in the laboratory before it is considered ready for external clinical evaluation.

II. *Prototype technical evaluation* is done to determine the performance, reliability, and safety of a new device. In this case, "prototype" means a device produced under near production conditions, usually by a private firm, but not yet offered for sale. Protocols are scientifically designed and tests are done in a technical facility. Criteria include manufacturer's specifications, industry standards, generally accepted scientific and engineering stan-

dards, and generally accepted health and safety standards.

III. *Prototype clinical evaluation* is done to determine the safety and effectiveness of a new device as used by a disabled person. Prototype is defined, as before, to mean a device ready for, but not in production and distribution. Methods range from subjective responses to scientifically conducted tests. Usually, a number of evaluation centers are involved with statistically significant numbers of subjects in the study so that results are meaningful. The outcome of a prototype clinical evaluation is usually a decision on whether or not a product, as tested, is commercially feasible.

The goal of prototype evaluation is as much to facilitate the movement of a new device or technique from development into commercial production as it is to complete technical and clinical evaluations. For this reason a change in design to overcome a problem may be permitted if the need arises very early in the evaluation. The important criteria is that, in the end, a sufficiently large and unchanged group of devices exists on which to base a statistically valid study.

IV. *Commercial Product Evaluation* is done to determine if the device should be made available to veterans by the various services that provide care and equipment. Procedures may be similar to those used in prototype evaluation but since products offered for sale are involved, no design or manufacturing changes are permitted. For VA developed devices that will have had extensive prototype evaluation, little additional commercial product evaluation is required, assuming the product is the same as the one evaluated. For non-VA developed devices, of which there are many, the need for effective commercial product evaluation is great.

In the Veterans Administration Prosthetic Services, Research, and Development, *in-house evaluation* is part of many research projects and is included in all development projects in the Rehabilitation R&D Program; *prototype technical evaluation* and *prototype clinical evaluation* are the responsibility of the Rehab R&D Evaluation Unit; and *commercial product evaluation* is the responsibility of the Prosthetic Assessment and Information Center. The Seattle Foot began as a research project and has moved through the above steps 1, 2 and 3. Because of the positive outcome of step 3, step 4 was waived and the Seattle Foot is now in commercial production and approved for use in the VA Prosthetic Service Clinics. This paper concerns the details of steps 2 and 3: the technical and clinical evaluation of Seattle Foot prototypes.

1. Research and In-house Evaluation

Prosthetic Research Study (PRS), obtained the collaboration of Model Instrument Works (MIW), Inc., a small private firm to assist in design and fabrication of the first 50 Seattle feet. These feet were fitted by the PRS to volunteer subjects. A preliminary *in-house* evaluation was done by Dr. Burgess and staff. This evaluation consisted of two sets of questions, the first directed to the prosthetist and the second to the subject. While the prosthetist's questions asked for some facts (such as time required to do various steps), both questionnaires were mainly subjective. The results of this study were very encouraging and certain subjects made dramatic improvement (mainly in sports) in their activities.

2. Procurement of Prototype

On the basis of Dr. Burgess's encouraging results the VA Rehab R&D Service made sufficient funds available to the VAMC Seattle so that the supply officer could contract with Model and Instrument Works, Inc. to produce 500 feet for clinical evaluation.

3. Determination of Evaluation Centers

The Prosthetics and Sensory Aids Service (PSAS) designated all 44 prosthetic clinics throughout the nation as clinical evaluation centers. Prosthetic clinic chiefs were given responsibility to recruit amputee subjects, order Seattle Feet and administer the evaluation documents. The PSAS made proper contract amendments to cover the cost of applying the Seattle Foot to either a new or existing prosthesis.

4. Ordering and Distribution of Feet

Sets of instructions including order forms for processing feet were sent to all clinic chiefs. (Appendix A, page 82). The completed forms with subject data were sent to the Rehab R&D Evaluation Unit. A data base system was created on the Unit's Tandy computer system using the Profile 16 application program which ran on the XENIX

operating system. Missing or ambiguous data were obtained by telephone follow-up—often a time-consuming task. After entry into the computer, order forms were forwarded to MIW for shipment of the foot (feet) to the prosthetic contractor who served the particular clinic.

Various reports were designed on the Profile 16-XENIX computer system including individual subject data and summaries with various counts and averages. Two of the summary reports are shown in Appendices B, page 83, and C, page 84. They provide interesting statistics about the 486 subjects included in the study.

5. Data Collection

Using the original sets of questions prepared by Dr. Burgess's staff in Seattle as a starting point, the staffs of the Prosthetic and Sensory Aids Service and the Rehab R&D Evaluation Unit prepared sets of questions to be answered by the clinic chiefs and the prosthetic contractors. (Appendix D, page 85). The contractor's questions were to be answered at the time of foot installation and the questions for the veteran subject were to be answered by the clinic chiefs one month following installation.

Because the staff of the Rehab R&D Unit wished to compute relatively simple statistics and present the results in an easily understood format, programs were written in BASIC language to handle the responses. In all, 272 completed forms were received and their data entered into the computer. A statistical summary of results gives the "bottom line" impact of the study. It shows that from every point of view and every category, the statistical averages (which are significant as shown by the standard deviations) indicate that most of the veterans found the Seattle Foot to be an improvement over the foot they had previously used. (See pages 80–81)

Ten of the most significant comment responses were stored in the computer and could easily be printed out. However, printing all 2,720 comments as an appendix to this paper was not deemed practical. Accordingly, only a brief selection of responses has been included to give the reader a flavor of their content. (Appendix E)

6. Prototype Technical Evaluation

Through an interagency agreement, the U.S. Army Natick Research, Development, and Engineering Center life-tested 6 Seattle Feet. This Center has the most advanced simulated walking machine available today. By adjustment, speed (steps per minute) and downward force (simulating various body weight) can be regulated to provide specific test conditions to emulate normal or accelerated walking.

Each foot was tested at 68 cycles per minute, approximating a 4-mile-per-hour walking rate. Downward pressure was adjusted to simulate the pressure exerted by a 175 pound bodyweight individual for whom the feet tested were made. Each sample prosthetic foot was subjected to 500,000 cycles of articulation (approximately 2 years equivalent). All feet withstood this test without change in performance or visible change in appearance. (Appendix F, page 90)

7. Exchange and Replacement Occurring During the Evaluation

Early in the evaluation, after 44 feet had been shipped by Model and Instrument Works (MIW), the foam in the region of the metatarsals began to fail. This problem obviously required a design change and, since only a few feet had been shipped, it was decided to permit MIW to make a change to solve the problem. It was done through the addition of a KEVLAR "toe pad" molded inside the foot over the tip of the energy absorbing keel in the region of the metatarsals.

In all, 93 feet were replaced representing 18 percent of all feet shipped. Reasons for these replacements are listed below:

Size exchange = 25	Wrong side shipped = 7
Incorrectly ordered = 5	Request for softer heel = 1
Request for stiffer keel = 1	Toe fractures = 2 (end of beam)
SACH style request = 7	Alignment problem = 1
Reshipment to Natick = 6	Foam failures = 30
Plantar-flexion breaks = 8	Returned = 28

As can be seen from the table, 40 feet were replaced due to failures of which 30 were foam failures. After the design change was made, only three foam failures occurred. The overall failure/replacement rate was 40/520 or 7.7 percent and after the design change, the failure/replacement rate was 13/476 or 2.7 percent. On either basis, these rates are very acceptable for a new prototype.

8. Conclusion

The Seattle Foot was provided to 486 amputee veteran subjects (of whom 59 were bilaterals) in a clinical evaluation project that involved 44 VAMC prosthetic clinic centers throughout the nation. Subjective responses that were obtained one month after fitting from 272 subjects

showed overwhelming enthusiasm and acceptance of the Seattle Feet as compared to the foot previously worn.

An accelerated life test of six Seattle Feet conducted by the U.S. Army Natick Research, Development and Engineering Center, Natick, MA, produced no failures and showed that the Seattle Foot, as represented by the six samples, survived 500,000 cycles of simulated 4-mile-per-hour steps for a 2-year equivalent use.

On the basis of these results, the Rehab R&D Unit recommended that the Prosthetic and Sensory Aids Service place the Seattle Foot on its approved list of prostheses to be supplied to veterans throughout the nation.

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                  VETERAN REACTION TO THE VA-SEATTLE FOOT

             Statistical Summary of Evaluation Study Comments

         As of: 06-05-1986          272  Subject Records Analyzed

1. How long did the Veteran take to adjust to the VA-SEATTLE FOOT?

     Average hours for 238 veterans = 20.5   Median =  0.6 hours

     [Median value is more meaningful since most veterans adjust quickly.]

2. Rating of Veteran's ability to perform activities using the
   VA-SEATTLE FOOT as compared to previous prosthetic foot.

                          Improvement in Ability

                              much                                  much
                              worse     worse      same     better   better
                                1         2         3         4        5
Activity        Num. Resp.      |.........|.........|.........|.........|

Run               172                                 ----------|----------
Jog               168                                 ----------|----------
Walk              254                                ----------|----------
Racket sports      86                              ----------|----------
Go upstairs       251                             ----------|----------
Go downstairs     249                            ----------|----------
Negotiate Terr.   250                            ----------|----------

                          Effort Required

                              much                                  much
                              less      less       same      more    more
                                1         2         3         4        5
Activity        Num. Resp.      |.........|.........|.........|.........|

Run               169          ----------|----------
Jog               163         ----------|----------
Walk              249          ----------|----------
Racket sports      85              ----------|----------
Go upstairs       247              ----------|----------
Go downstairs     246              ----------|----------
Negotiate Terr.   245            ----------|----------

                Key:   | indicates mean;  ----- indicates std. dev.

3. How does the Veteran rate the stiffness of the heel?

     Too soft  ****

     Optimum   ****************************************

     Too firm  ********

4. How does the Veteran rate the weight of the foot?

     Too light

     Optimum   ************************************************

     Too heavy ****
```

5. How has Veteran's endurance level in sports changed?

```
Decreased *
Same      ***************
Increased **********************************
```

Key: Each * indicates five responses.

6. How does the Veteran rate the 'spring-back' action of the foot?

```
                                too                                  too
                                little          optimal              much
                                  1        2        3        4        5
Activity        Num. Resp.        |........|........|........|........|

Run               172                       -------|-------
Jog               165                        -------|-------
Walk              252                        -------|-------
Racket sports      91                        ------|------
Go upstairs       247                         ------|------
Go downstairs     240                        ------|------
Negotiate Terr.   252                        -------|-------
```

7. Has the shock stress to the Veteran's hip, knee or limb . .?

```
Decreased      *************************
Same           ************************
Increased      ***
```

8. If the Veteran has experienced skin problems, have they . .?

```
Decreased      ******
Same           *****************
Increased      **
No problems    *************************
```

9. How does the Veteran rate the foot as a replacement?

```
Satisfactory   *********************************************
No difference  ***
Unsatisfactory *****
```

10. Is the cosmesis of this foot satisfactory?

```
Yes       ********************************************
No        ******
```

Key: Each * indicates five responses.

11. Does the Veteran consider the VA-SEATTLE FOOT to be an overall improvement over previous prosthetic feet?

```
                                much                                 much
                                worse     worse     same     better    better
                                  1        2        3        4        5
                                  |........|........|........|........|
                                                     --------|--------
Number of responses= 264
```

APPENDIX A

Order Form

1. The following information concerning this amputee veteran is being furnished for your consideration of the veteran as a possible candidate for the evaluation of the Seattle Foot:

Name _____
Address _____
_____

Telephone (H) _____
(W) _____

VA Limb Contractor
Name _____
Address _____
_____

Telephone _____

VETERAN DATA:
Age _____ Weight (clothed, with prosthesis) _____ Shoe size _____
Amputation: Date _____ Side _____ Level _____ Length _____
Type of prosthesis currently in use _____

Use of prothesis _____ hours per day.

Physical activities in which the veteran is actively involved:

ACTIVITY	TIMES/WEEK	HRS/WEEK	ACTIVITY	TIMES/WEEK	HRS/WEEK
Running			Tennis		
Walking			Golf		
Baseball			Skiing		
Basketball			Bowling		
Hiking			Fishing		
Jogging			Hunting		
Racquetball			Other		

2. The VA-SEATTLE FOOT™ is designed with materials that can be altered for unique requirements of the individual. The information needed to determine the correct size and type of The VA-SEATTLE FOOT™ is based on the individual's peak activity levels (e.g., sprint running, jogging, jumping, etc.).

a. Is the veteran interested in upgrading his/her present activity level, in what ways would this be done, and what are the activity goals?

_____
_____
_____

b. The VA-SEATTLE FOOT™ is designed to return as much energy as is put into it. To select the appropriate foot it is important to know how aggressive the veteran is in applying this energy. How would the veteran rate his/her aggressiveness in physical activities compared to other amputees with similar functional limitations.

( ) Low ( ) Medium ( ) High

3. Please advise this office on the acceptance or rejection of the veteran in the clinical evaluation of the Seattle Foot.

_____ SIGNATURE

_____ DATE

APPENDIX B

Summary Report

VA Seattle Foot Subject Data (as of Feb. 12, 1986)
Breakdown of Subject Requests by Shoe Size

Shoe Size	Left Foot	Right Foot	Bilaterals	Total Subjects
Under 8.0	12	9	3	24
8.0	14	18	4	36
8.5	13	10	3	26
9.0	45	42	17	104
9.5	36	31	11	78
10.0	31	31	11	73
10.5	23	21	4	48
11.0	27	25	6	58
11.5	8	4	—	12
12.0	6	8	—	14
Over 12.0 (NA)	6	3	—	9
TOTALS:	221	202	59	486

Totals by Weight

Under 145	41
145–175	180
176–205	182
206–235	62
Over 235	21

Average Weight: 180.0

Totals by Age

Under 30	27
30–40	255
41–50	61
51–60	80
61–70	59
Over 70	3

Average Age: 43.2

Grand total of all feet requested (including 2 each for bilaterals):	541
Total requests forwarded to MIW:	442
Total refused because of outsize:	40
Grand total of all MIW shipments (of which 58 include 2 for bilaterals):	454

APPENDIX C

VA Seattle Foot Evaluation (as of Feb. 12, 1986)
Subject Data Averages

Total Number of Subjects: 486 (Total Requests)

Number of Left Side: 221
Number of Right Side: 204
Number of Bilaterals: 59

Number of AK: 76
Number of BK: 368

(Includes bilaterals when both are AK or BK, therefore sum is greater than sum of left plus right)

Number of Low Agressiveness: 14
Number of Medium Agressiveness: 127
Number of High Agressiveness: 329

Averages of all 486 Subjects

Age: 43.2 years
Weight: 180 pounds
Shoe Size: 9.6
AK Amputation Length: 10.2 inches
BK Amputation Length: 5.7 inches
Use Hours Per Day: 15.2 hours

Activities Averages for 486 Subjects

Activity	*Times per Week*	*Hours per Week*	*Activity*	*Times per Week*	*Hours per Week*
Running	.6	.6	Tennis	.2	.4
Walking	5.1	23.4	Golf	.7	2.2
Baseball	.3	.7	Skiing	.3	.9
Basketball	.4	.5	Bowling	.4	.7
Hiking	.5	1.2	Fishing	.9	3.2
Jogging	.3	.3	Hunting	.5	2.1
Racquetball	.2	.3	Other	1.0	3.0

APPENDIX D

Clinic Chief/Prosthetic Contractor Questionnaires

NAME OF VETERAN _____

Amputation Date _____ Side _____ Level _____

Age _____ Weight _____ Shoe Size _____

Prosthetic Facility _____

Address _____

_____

Prosthetist's Name _____

PART I
Questions to be Answered at Time of Foot Installation by the Prosthetic Contractor

1. What type of prosthesis and what components does the veteran use:

   Prosthesis socket: _____ Heel height: _____

   Knee joint: _____ Shoe type: _____

   Rotator: _____ Foot type: _____

   Interface (liner): _____ Endoskeletal: _____

   Suspension: _____ Exoskeletal: _____

2. Has the VA-Seattle Foot been attached to:
   ( ) a special prosthesis—please describe prosthesis

   _____

   ( ) a prosthesis for daily use

3. Is the heel height: ( ) too low ( ) optimal ( ) too high

4. Rate the subject's previous foot-heel cushion:
   ( ) soft ( ) medium ( ) firm

5. Rate the VA-Seattle Foot heel cushion:
   ( ) soft ( ) medium ( ) firm

6. Was the prosthesis realigned to this new foot:

   Yes _____ No _____

   If the answer is no, what type of foot was the prosthesis aligned for:
   ( ) SACH
   ( ) Griessinger
   ( ) Two-way ankle
   ( ) SAFE
   ( ) Other. Describe _____

7. How long did it take to align this foot: _____

8. Dropping a plumb line from the middle of the posterior brim to the floor, the foot attachment bolt is, in relation to this line:

   ( ) medial ( ) lateral to the string by _____ inches

9. Dropping a plumb line from the middle of the lateral side of the socket to the floor, the foot attachment bolt is, in relation to this line:

   ( ) anterior ( ) posterior to the string by _____ inches

10. List the number of degrees of socket:
( ) flexion or ( ) extension
( ) adduction or ( ) abduction

11. Is the elastic springback of the foot adequate in meeting the activity level requirements of the subject:

Please describe _____

_____

12. Describe any problems encountered in fitting the VA-Seattle foot and measures taken to resolve them:

_____

_____

PART II
Questions for the Veteran to be Administered by the Prosthetics Clinic Chief (one month following installation)

13. Physical activities in which the veteran is involved:

ACTIVITY	HRS/WEEK	ACTIVITY	HRS/WEEK
Running		Aerobics	
Jogging		Jump Rope	
Walking		Golf	
Hiking		Skiing	
Baseball		Bowling	
Racquet Sports		Hunting	
Volleyball		Other	

14. Is the VA-Settle Foot used for:
( ) only sports activities
( ) all daily activities including sports
( ) only occasionally. Please explain: _____

_____

15. Did the veteran go back to wearing a different foot. If so, for what activities and why: _____

_____

16. How long did it take the veteran to adjust to the VA-Seattle Foot: _____

17. Please rate the veteran's ability to perform the following activities using the VA-Seattle Foot as compared to previous prosthetic feet:
1 = less 3 = same 5 = more

	IMPROVEMENT IN ABILITY					EFFORT REQUIRED				
	1	2	3	4	5	1	2	3	4	5
a. run										
b. jog										
c. walk										
d. racket sports										
e. go upstairs										
f. go downstairs										
g. negotiate uneven terrain										

18. How does the veteran rate the stiffness of the heel cushion of this new foot:
( ) too soft ( ) too optimal ( ) too firm

19. How does the veteran rate the weight of this new foot:
( ) too light ( ) optimal ( ) too heavy

20. As the veteran performs sports activities with this new foot, has his endurance level:
( ) decreased ( ) remained the same ( ) increased

21. Rate the "spring back" action detected through the VA-Seattle Foot as it is used in daily activities:
1 = too little 3 = optimal 5 = too much

SPRING BACK

	1	2	3	4	5
a. run					
b. jog					
c. walk					
d. racket sports					
e. go upstairs					
f. go downstairs					
g. negotiate uneven terrain					

22. Generally, would the veteran prefer more or less toe spring back (toe flexion at push off): _____

23. Compare the ease of achieving a natural gait using the VA-Seattle Foot with previous prosthetic feet in:

Walking:

Running:

24. Has the shock stress to the veteran's hip, knee or limb
( ) decreased ( ) remained the same ( ) increased

25. If the veteran has experienced skin problems, have they
( ) decreased
( ) remained the same
( ) increased
( ) no skin problems

26. How does the veteran rate the VA-Seattle Foot as a permanent replacement for his previous prostetic foot:
( ) satisfactory
( ) no significant difference
( ) unsatisfactory

27. Is the cosmesis of this foot satisfactory:

Yes _____ No _____ Please explain _____

28. Does the veteran consider the VA-Seattle Foot to be an overall improvement over previous prosthetic feet:

_____

29. Does the veteran have any other comments, suggestions, or criticisms with regard to this foot design that might help us improve it for other amputees:

_____

30. Does the veteran have any suggestions regarding future areas of research that he considers important:

_____

31. If you have any questions concerning this report, please contact my office, FTS _____

_____ _____
(signature) Date
Prosthetic Clinic Chief

APPENDIX E

Selected Responses of Prosthetists and Veterans to Questions Regarding the Seattle Foot

Question No. 7 (To the prosthetist) How long did it take to align this foot?

Answers to this question were numeric. Average minutes required = 87.4; Median minutes required = 60 minutes. (Median time may be more significant since a few "long times" will skew the distribution).

Question No. 11 (To the prosthetist) Is the elastic springback of the foot adequate in meeting the activity level requirements of the subject?

* Yes, veteran's springback effect was greater making exercising and ambulation easier.
* Has been working so well that the veteran does not feel it; performance greatly improved.
* Veteran can't feel springback, but can do more activities with less effort.
* Veteran describes it as too springy.
* Veteran says feet require less energy to ambulate; snow skis comfortably (down hill).
* Springback is exceptional, particularly in sporting activities. Veteran is very pleased with its function.
* Best that the veteran has ever had; thinks it great.
* Veteran is very active; likes the function of the VA Seattle Foot very much.
* Yes, veteran does a lot of fishing, hunting, and walking and is now doing some running.
* Veteran did not like Seattle Foot; wanted multi-axis foot back.

Question No. 12 (To the prosthetist) Describe any problems encountered in fitting the VA-Seattle Foot and measures taken to resolve them?

[More than half of the answers were "None or no comment"]

* Change over from SAFE Foot was relatively easy, incorporating and adjustment for plantar flexion wedge.
* Re-drilled holes, changed alignment, lack of corregation on top of foot makes it difficult to glue.
* No problems, some alignment was used.
* Had to plantar flex it considerably and counter sink it for ROL bearing which weakens its keel.
* No special problems; alignment seemed much the same as any PTB with SACH foot.
* No special problems; patella tendon bearing prosthesis does not function well if socket is not in flexion.
* Only problem, attachment bolt seemed short as only 3/8 in. would catch in the threads; installed longer bolt.
* Had to decrease static alignment dorsiflexion, and shorten heel lever arm alignment, otherwise a pleasing attitudinal response.
* Veteran wanted more spring action; moved foot forward very maximal and still did not get desired function.
* Knee instability, most likely due to firmer heel cushion, but as we progressed with dynamic alignment fitting we were able to adjust this problem.

Question No. 23a (To the veteran) Compare the ease of achieving a natural gait using the VA-Seattle Foot with previous prosthetic feet in walking.

* Much easier; you feel that you have more control of foot.
* Veteran could not believe how natural and easy to walk and run with prosthesis.
* The endurance level has increased and ease of walking has increased considerably.
* Difference between night and day; feels like old leg is back; feels so natural.
* Best foot veteran has had in 41 years of wearing a prosthesis.
* Difficulty, especially standing.
* Vet can walk all day and still feel as though he would like to do more.
* Has greatly improved natural gait; seems to perform much like natural foot.
* Not as good, too hard on heel contact.
* Family noticed a great improvement in ability to do everything better.

Question No. 23b (To the veteran) Compare the ease of achieving a natural gait using the VA-Seattle Foot with previous prosthetic feet in running.

* Was amazed. 'There were tears in my eyes'.
* Much easier—never could run w/2-way foot.
* Veteran is AK; has attempted to run but cannot.
* With effort.
* Have now started to run and jog short distances w/success and comfort to stump.
* Seattle Foot is very good.
* Great improvement in running gait.
* Great, but knee does not stay up with me.
* Great—can't run with old foot.
* Never ran before; can now easily lift my leg as I run.

Question No. 27 (to the veteran) Is the cosmesis of this foot satisfactory?

* Too pale; it looks like a cadavers foot.
* Socially acceptable—love it.
* Veteran never had toes before and was surprised.
* He liked its life-like look, but never removes his shoe.
* Psychologically uplifting; family's opinion really favorable.
* It's ok; a little too wide; wrong color (Filipino).
* Color needs to be more flesh-like, too light a color.
* Width of foot is too great; is unnatural compared to natural foot in soft shoes.
* Feels the cosmesis is great—likes to show friends.
* Looks fine; veteran black and coating rubs off; it bleeds white.

Question No. 28 Does the veteran consider the VA-Seattle Foot to be an overall improvement over previous prosthetic feet?

* Yes, veteran walked into vendor with crutches, walked out without crutches.
* Yes, best ever had—39 yr. amputee.
* Yes, best foot he has ever had besides his own.
* For running and jogging only.
* Improvement over SACH for sports but little difference from 5-way foot.
* Yes, it has basically improved his endurance and walking ability.
* Likes quietness of foot; overall improvement.
* An unqualified Yes!
* No
* Yes, for the young and active person.

APPENDIX F

Testing of Prosthetic Foot—VA Seattle Foot
A Report of the U.S. Army Natick Research, Development and Engineering Center

PREFACE

This work represents efforts to simulate the normal walking conditions which would occur over a period of 500,000 steps, using sample experimental prosthetic feet, as would be worn by an amputee in the performance of his daily activities.

INTRODUCTION

The objective of this report is to describe the testing and evaluation performed on the VA-SEATTLE FOOT.

As part of its ongoing R&D program, the Rehabilitation R&D Service of the Veterans Administration developed a new prosthetic foot. This foot contains features considered significantly improved when compared to the present prosthetic foot provided handicapped patients at VA Hospitals.

In conjunction with this mechanical evaluation of the VA-SEATTLE FOOT, at Natick, large scale clinical trials were scheduled by the Veterans Administration to determine the clinical value of the foot.

The U.S. Army Natick Research, Development and Engineering Center has the most advanced simulated walking machine available today. By adjustment, speed (steps per minute) and downward force (simulating various body weights) can be regulated to provide specific test conditions.

Six sample prosthetic feet sent directly from the manufacturer, Model and Instrument Works Inc., Seattle, WA, were furnished this Center for evaluation. All samples appeared similar when viewed externally, however, different designation numbers were imprinted on each sample.

Individual cyclic testing of each sample prosthetic foot was performed on the Boot/Shoe Tester to determine the durability of that sample.

METHODS AND MATERIALS

Methods and Sample Preparation

Simulated walking characteristics were applied to each sample prosthetic foot by the Boot/Shoe Tester, (**Figure 1**) a speed of 68 cycles per minute, approximately a four mile per hour walking rate.

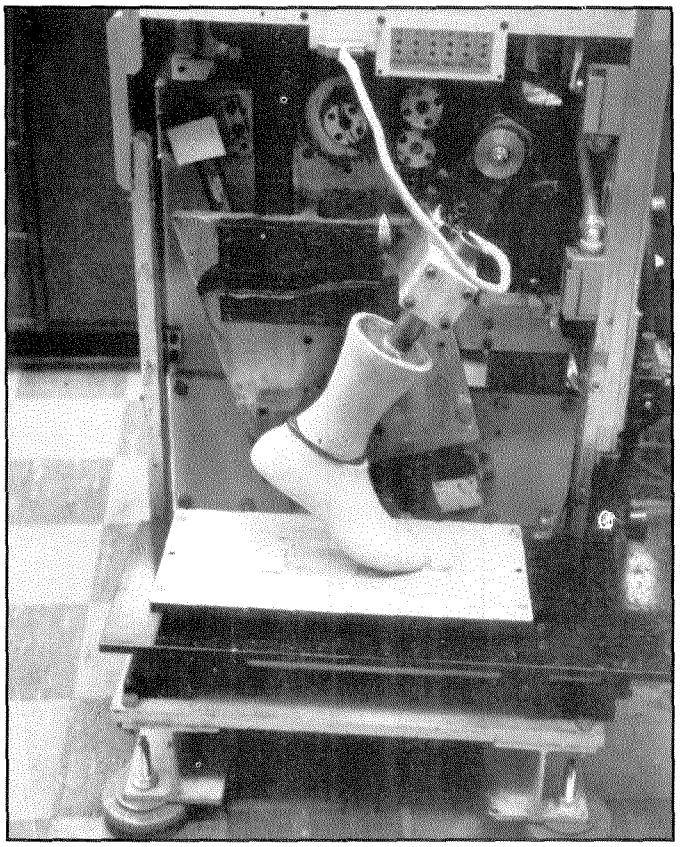

Figure 1.
Boot/Shoe tester, cover raised for visibility

All samples were evaluated as received with one minor modification. A small hole was drilled in each sample at the top rear section of the rigid plastic insert, to allow insertion of a stabilizing pin contained on the equipment (**Figure 2**).

Each prosthetic foot sample was covered with a standard military sock, (**Figure 3**) low quarter shoe, (**Figure 4**) and attached to the machine for simulated walking exposure. Samples were removed every 25,000 cycles, uncovered, examined for failures, recovered, and remounted for further cycling. **Figures 4** and **16** give examples of flexing encountered during testing. Downward pressure was adjusted to simulate the pressure exerted by a 175 pound body weight individual. All samples of the prosthetic foot were subjected to 500,000 cycles of articulation.

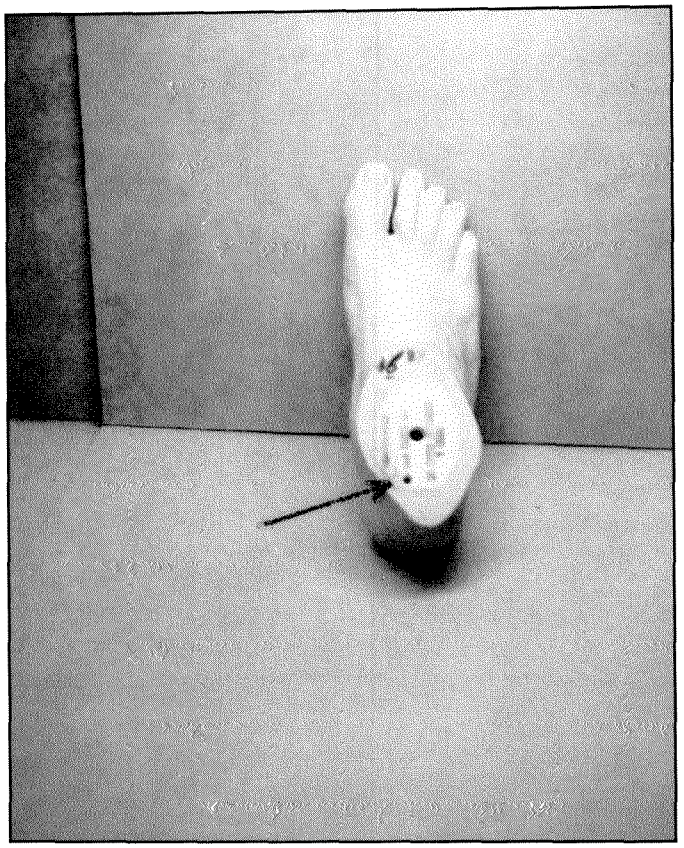

Figure 2.
Modification to VA-SEATTLE FOOT for stability during testing

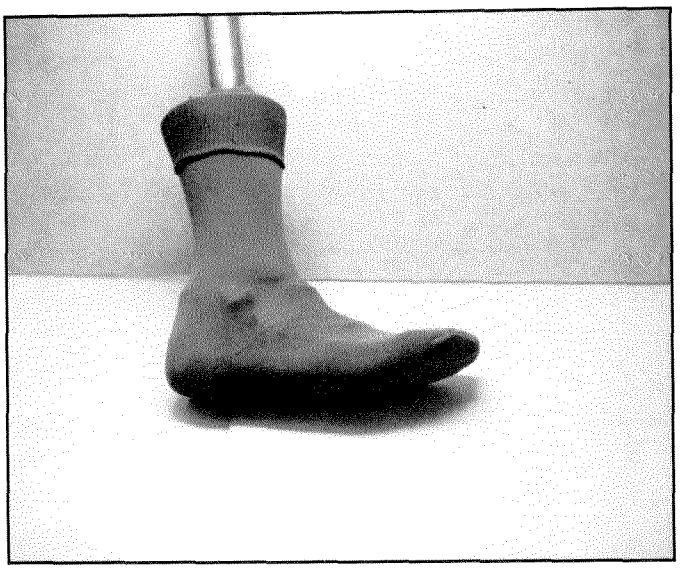

Figure 3.
VA-SEATTLE FOOT with standard sock

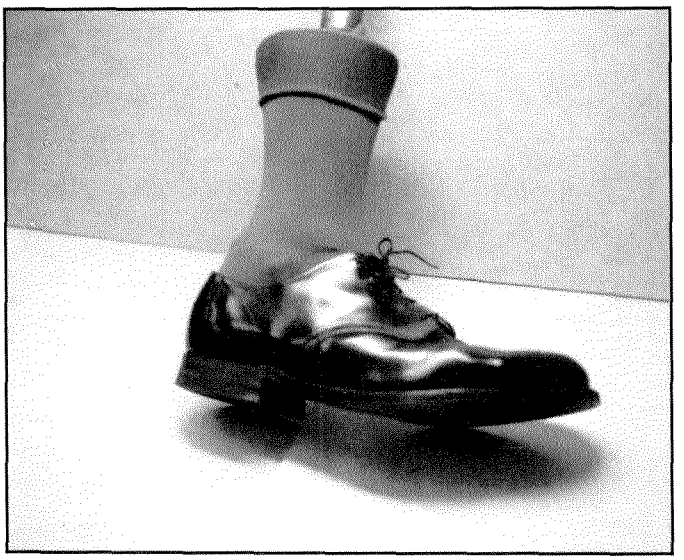

Figure 4.
VA-SEATTLE FOOT with standard sock and shoe, as tested

Materials

1. Six VA-SEATTLE FOOT samples sent from the Model and Instrument Works Inc., Seattle, WA, at the request of the VA Rehabilitation Research and Development Evaluation Unit were furnished the Natick RD&E Center. Samples were designated as "SEATTLE FOOT FOR TESTING, SIZE 9 RIGHTS, WITH TOE PADS, 15DS, 70-55, 56, 58, 59, 96 and 99.
2. Shoe, Mens, Dress Oxford, Size 9R, in accordance with Military Specification MIL-S-13192 M Federal Stock No. 8430-00559-4261.
3. Socks, Mens, Nylon Cushion Sole, Stretch Type, OG 106 in accordance with Military Specification MIL-S-43823A, Federal Stock No. 8440-00-439-2131.

RESULTS

The results obtained from subjecting each sample prosthetic foot to preestablished cycling repetitions of 500,000 cycles or failure, whichever occurred first, showed all sample units capable of meeting the maximum 500,000 cycles with no visible failures.

All samples were examined prior to testing for visible flaws, cracks, cuts or other conditions indicating weaknesses or possible areas of later failure.

Repetitive examinations of each sample prosthetic foot throughout each test run showed no abrasion, wear or otherwise visible change in any foot, from its original condition.

DISCUSSION AND CONCLUSIONS

Samples all appear similar by visual examination, both initially and after completion of 500,000 flexing cycles.

Any difference in sample foot construction is not externally obvious when viewing each sample by its designation number.

All samples are considered equally durable since each sample was capable of attaining the maximum established limits of the test.

It is recommended that samples be cut lengthwise from toe to heel to determine whether any internal delamination of keel and outer covering, or internal component failure resulted from mechanical testing.

This evaluation was considered a much harsher test than one conducted by personnel wear testing, due to the continual non-stop flexing at a rapid speed and the potential heat build-up.

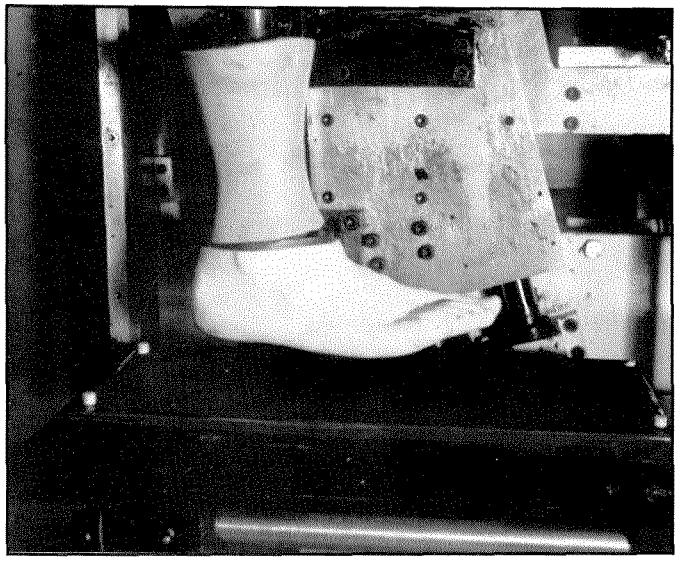

Figure 5.
VA-SEATTLE FOOT, simulation, approaching heel strike

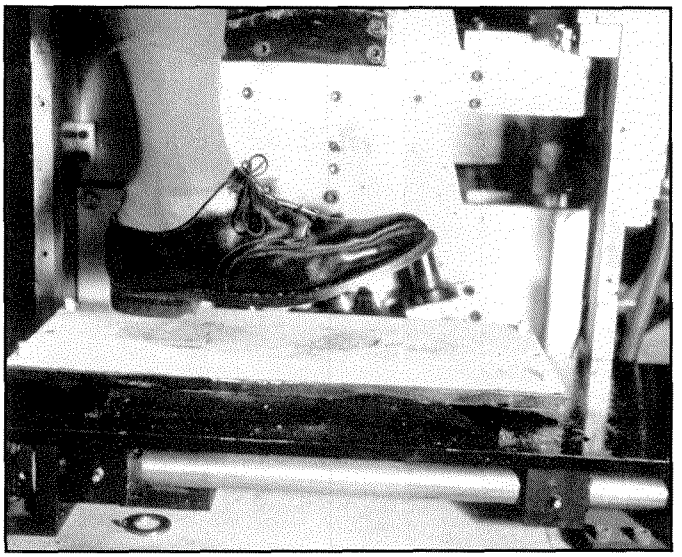

Figure 6.
VA-SEATTLE FOOT, actual test condition, approaching heel strike

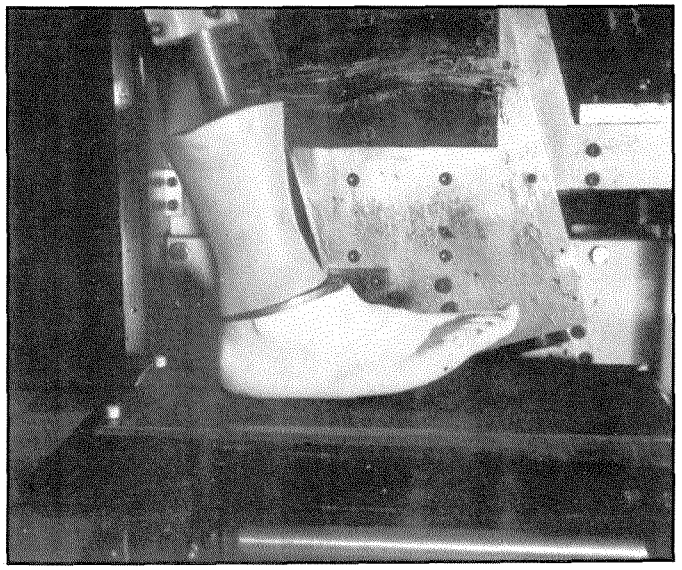

Figure 7.
VA-SEATTLE FOOT, simulation, heel strike position

Figure 8.
VA-SEATTLE FOOT, actual test condition, heel strike

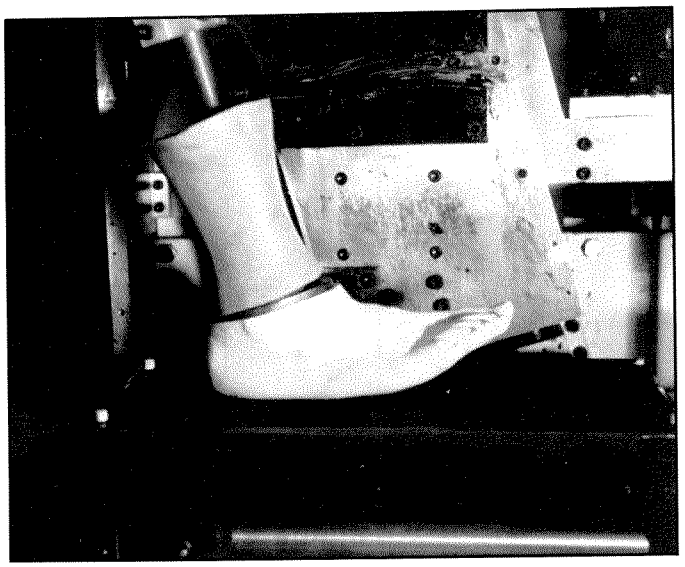

Figure 9.
VA-SEATTLE FOOT, simulation, downward pressure rolling forward off heel

Figure 10.
VA-SEATTLE FOOT, actual test condition, downward pressure rolling forward off heel

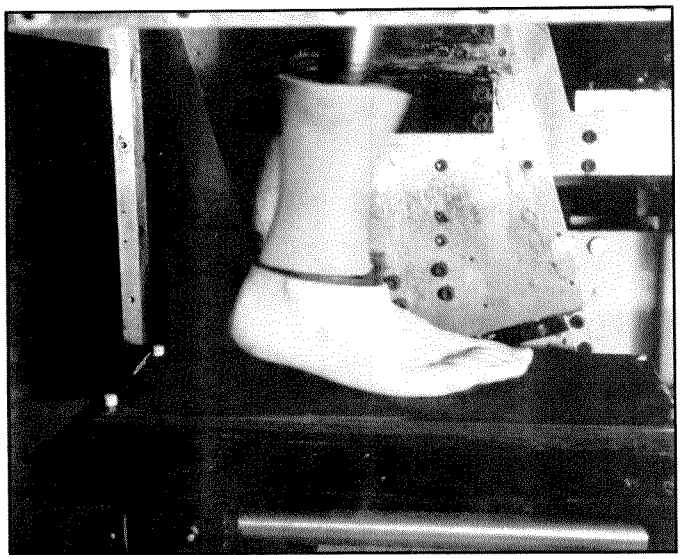

Figure 11.
VA-SEATTLE FOOT, simulation, pressure approaching ball of foot

Figure 12.
VA-SEATTLE FOOT, actual test condition, downward pressure approaching ball of foot

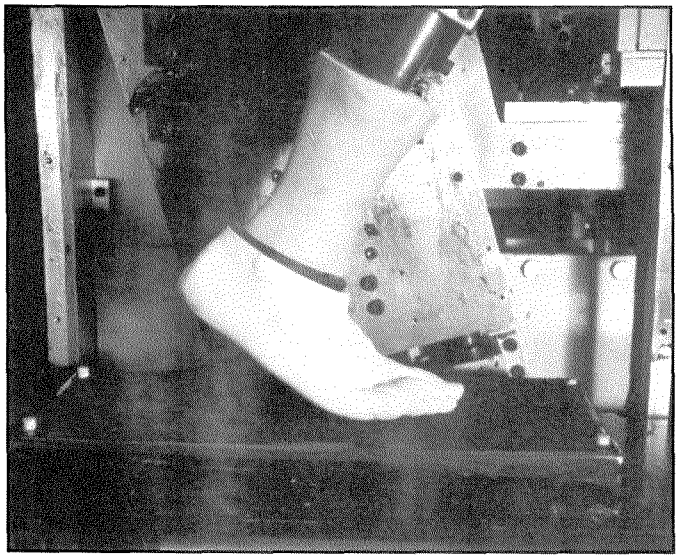

Figure 13.
VA-SEATTLE FOOT, simulation, downward pressure on ball of foot

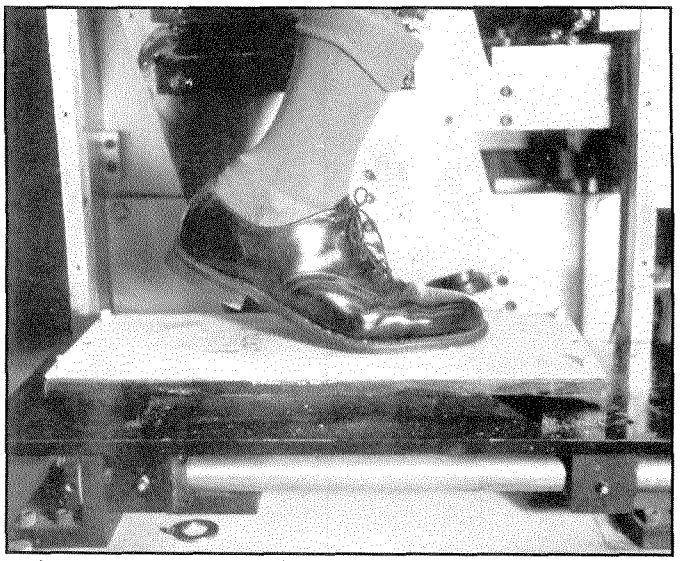

Figure 14.
VA-SEATTLE FOOT, actual test condition, downward pressure on ball of foot

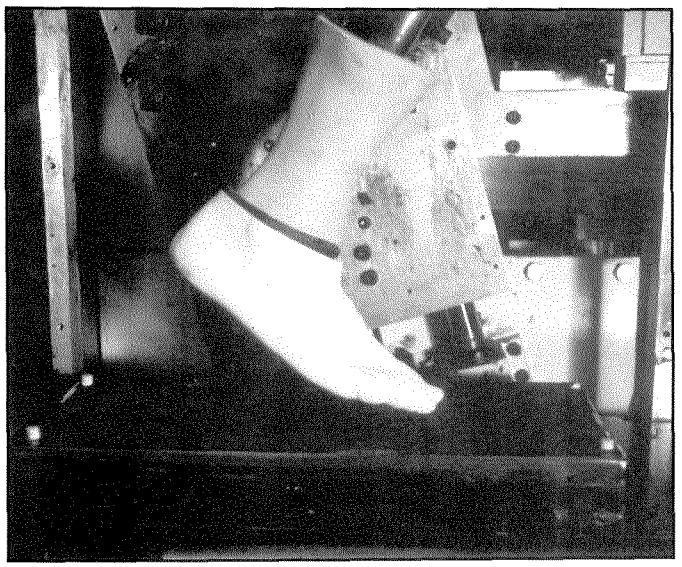

Figure 15.
VA-SEATTLE FOOT, actual test condition, lift-off from ball of foot

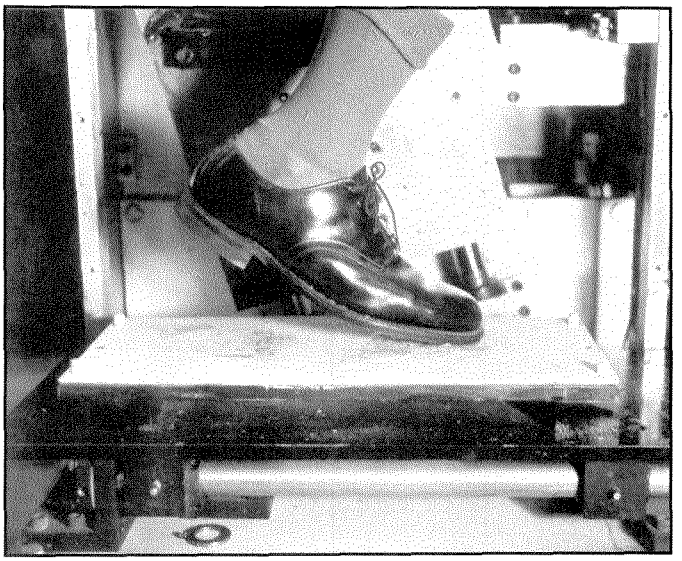

Figure 16.
VA-SEATTLE FOOT, actual test condition, lift-off from ball of foot, beginning of recycling