

THE SHAPE AND ROLL PROSTHETIC FOOT: Design and Development of Appropriate Technology for Low-Income Countries (1)

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INTRODUCTION

Our examination of roll-over shapes of prosthetic and able-bodied ankle-foot systems suggests that “high-performance” prosthetic feet conform to geometries that are similar to the shape taken by the biologic ankle-foot system in walking. This may be beneficial since the prosthetic foot is meant to replace the function of the missing foot and ankle.

We have developed the *Shape and Roll* foot using the able-bodied ankle-foot roll-over shape as a goal. The *Shape and Roll* foot is manufactured using simple, low-cost technologies (e.g. compression molding of co-polymer plastic, sawing, and drilling) and can be easily customized to the height, weight, and foot length of the client. Our initial investigations of the *Shape and Roll* foot have included (1) Fatigue testing, (2) Clinical testing in the United States, and (3) in El Salvador.

FATIGUE TESTING OF THE FOOT

A fatigue testing apparatus was developed in our laboratory to help determine the durability of the *Shape and Roll* foot (Figure 1). The system contains two pneumatic pistons that repeatedly load the heel and forefoot of the prosthetic foot. The apparatus uses pressure switches to estimate the loads applied and has a counter that increments after each cycle.

Thus far three prosthetic feet have been successfully tested to 3.8, 2.8, and 2.2 million cycles. The ISO standard for fatigue testing of prosthetic feet requires 2 million cycles without failure.

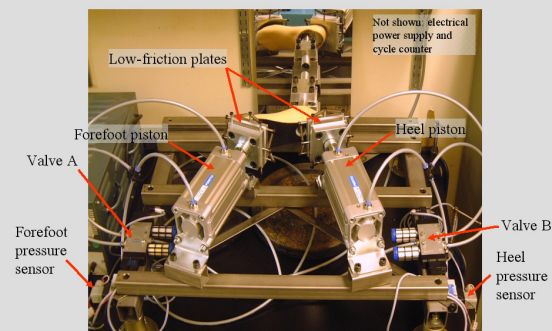


Figure 1 – Prosthetic Foot Fatigue Testing Apparatus

CLINICAL TESTING IN THE UNITED STATES

Clinical testing of the *Shape and Roll* foot has been completed in the United States. Ten persons—aged between 32 and 63 years—with unilateral trans-tibial amputations participated in the study (See Table below). Each participant—three females and seven males—used the *Shape and Roll* foot for a period of three weeks. Each person completed a questionnaire on their current prosthetic foot and on the *Shape and Roll* foot.

Protocol:

- A copy of the current prosthetic socket was obtained using Pedilen® Duplication Plastic (Otto Bock).
- Testing prostheses were fabricated and fitted with the *Shape&Roll* Foot (SR).
- First gait analysis session—three walking speeds—with current prosthetic foot (CF) was performed at the VACMARL gait laboratory, serving as a base line; “In-house” questionnaire 1 was filled out regarding walking capability with CF; Switching to testing prosthesis; Second gait analysis session followed immediately after initial fitting with SR foot.
- Participants were requested to wear the testing prosthesis with the SR foot for three weeks.
- Third gait analysis session after completion of the three testing weeks; “In-house” questionnaire 2 was filled out regarding the walking capabilities with SR and specific questions towards SR.

Anthropometric Data of the USA Participants	
Variables	Participants (n = 10)
Age (years)	47 ^a (32 – 63 ^b)
Height (m)	1.86 (1.73 – 1.88)
Weight (kg)	85.2 (82.0 – 124.5)
Post-amputated (years)	5.0 (1.5 – 33.0)
Amputation Reasons	
Traffic accident	4 (40)
Peripheral Vascular Disease	2 (20)
Meningococemia	1 (10)
Cancer	1 (10)
Osteomyelitis	1 (10)
Unknown	1 (10)
Current prosthetic feet	
College Park	2
Flex Walk	2
Flex-Reflex VSP	1
Flex Foot	1
Masterstep	1
Seattle	1
Seattle light	2

^a Median; ^b Minimum/Maximum; ^c Frequency(Percentage)

Results:

Data analysis is ongoing. The results of the “In-house” questionnaire revealed no significant differences between participants’ performance while wearing the SR foot compared to the CF. Analysis of the gait data will show if this result is also valid for the quantitative walking measurements.

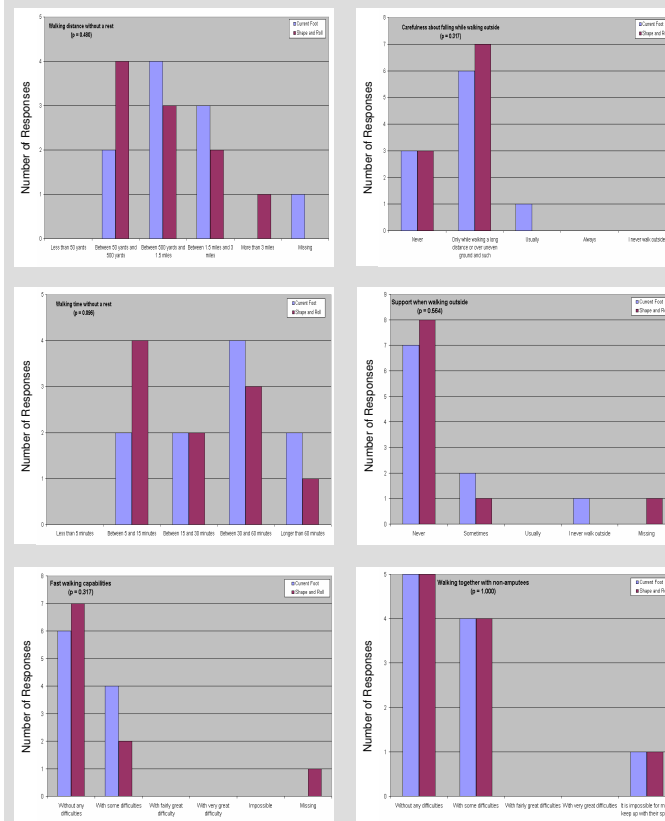


Figure 2 – Questionnaire Results (n=10).
p-value associated with Wilcoxon Signed Ranks Test

ACKNOWLEDGMENTS

This work was partially funded by the National Institute on Disability and Rehabilitation Research (NIDRR) of the U.S. Department of Education under grant No. H133E980023. The opinions contained in this publication are those of the grantee and do not necessarily reflect those of the Department of Education.

This work was also funded by the Center for International Rehabilitation (CIR), Chicago. We would like to acknowledge Cecilia Novoa and Fred Navarrete, CIR El Salvador, and FUNTER (Fundación Teletón Pro-Rehabilitación) for their thoughtful assistance and patient referrals.