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CLINICAL REPORT

Report on the Evaluation of the DAV/Seattle Knee

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Abstract—The Department of Veterans Affairs (VA) Rehabilitation Research and Development Service, Technology Transfer Section (TTS) managed a clinical evaluation of the DAV/Seattle Knee with collaboration from the Prosthetic and Sensory Aids Service (PSAS), VA Central Office (VACO) at 16 VA Medical Facilities, recruiting 46 subjects. The DAV/Seattle Knee was designed to provide a functional, lightweight artificial knee that would give veterans, with above-knee amputations, greater mobility than they experienced with other comparative man-made knees. This national evaluation was conducted to determine the acceptance of the DAV/Seattle Knee by veterans prescriptive criteria and to determine what modifications, if any, were needed to improve the product for optimal use by the targeted population and to enhance its marketability.

TTS, with collaboration from PSAS/VACO, managed a clinical evaluation on 28 units with fluid swing control. The evaluation trials were conducted between May 1992 and May 1993. During the initial phase of the clinical trials, a common problem of the piston shaft end breaking was identified. This was a fail-safe situation; the knee support structure maintained its integrity and did not cause the subject to fall. All units were immediately returned to the manufacturer for installation of new damper mounts.

Forty-six subjects were accepted; 28 fitted; 23 completed evaluation for 30 days, 8 subjects are currently wearing the DAV/Seattle Knee. The subjects' responses from the clinical trials successfully demonstrated that the DAV/Seattle Knee is safe and reliable when properly matched to the user's weight, stump length, and activity requirements.

Key words: *above-knee amputees, lightweight artificial knee, piston shaft, pylon,*

INTRODUCTION

The Department of Veterans Affairs (VA) Rehabilitation Research and Development Service (Rehab R&D), Technology Transfer Section (TTS) managed a clinical evaluation of the DAV/Seattle Knee with collaboration from the Prosthetic and Sensory Aids Service, VA Central Office (PSAS/VACO). The DAV/Seattle Knee was developed by Ernest M. Burgess, MD, Director, Prosthetics Research Study (PRS) Seattle, Washington, and designed by Alan Aulie, Research Engineer with the PRS. This work was supported by the Department of Veterans Affairs, Rehabilitation Research and Development Service, and the Disabled American Veterans' (DAV) Charitable Service Trust.

The DAV/Seattle Knee was developed through the use of research and design methodology, including extensive tests of amputee veterans using the prototypical knee. As a result of successful tests, Dr. Burgess made design refinements to the Knee and indicated that the current version was ready for field testing outside the development environment. TTS, with collaboration from PSAS/VACO, conducted

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this field study to determine if this new knee should be made commercially available and prescribed for veteran beneficiaries.

REVIEW OF DEVELOPMENT

Within the scope of the VA's continuum support of PRS, Dr. Burgess initiated this research in response to a need for an artificial knee that is lightweight, stable, has minimal parts (reduced cost and maintenance and repair), and provides amputee veterans with greater mobility than they have experienced with other comparably priced artificial knees. Two versions of the DAV/Seattle Knee were developed. One Knee has fluid swing control with optional adjustable friction; the other has adjustable friction control only. TTS, with collaboration from PSAS/VACO, managed a clinical evaluation on 28 units with fluid swing control.

PURPOSE

This national evaluation was conducted to determine the acceptance of the DAV/Seattle Knee by veterans and to determine what modifications, if any, were needed to improve the product for optimal use by the targeted population, and to enhance its marketability. Specific areas scrutinized in this evaluation were: 1) prescription indications and contra-indications; 2) fitting, compatability with existing componentry; 3) functional use and activities; 4) gait enhancement; 5) comparative acceptance to other prosthetic knees; 6) stability of knee while walking and standing on flat surface and other terrain; 7) reliability; 8) maintenance and repair; 9) durability; and, 10) readiness for commercial availability (changes required for marketing and application).

DESCRIPTION

Physical Appearance

The basic structure of the DAV/Seattle Knee is machined from nylon 6/6 instead of the heavy metal components (springs and hinges) that make up many traditional artificial knees. Its light weight (1.25 pounds), should allow above-knee amputees to walk with greater fluidity and mobility than with other comparably priced artificial knees. A unique feature of the Knee is the simplicity of its design. It is made from a single piece of plastic designed so as to mimic certain forces while walking, such as the spring in one's step and the push-off from the toe. The knee component of the DAV/Seattle Knee is a dynamic structure that bends and straightens out, replacing a function that used to take dozens of mechanical parts (**Figure 1**). Lower cost is another feature of the DAV/Seattle Knee. The total cost of the production Knee will be significantly less than a current comparable knee (**Table 1**).

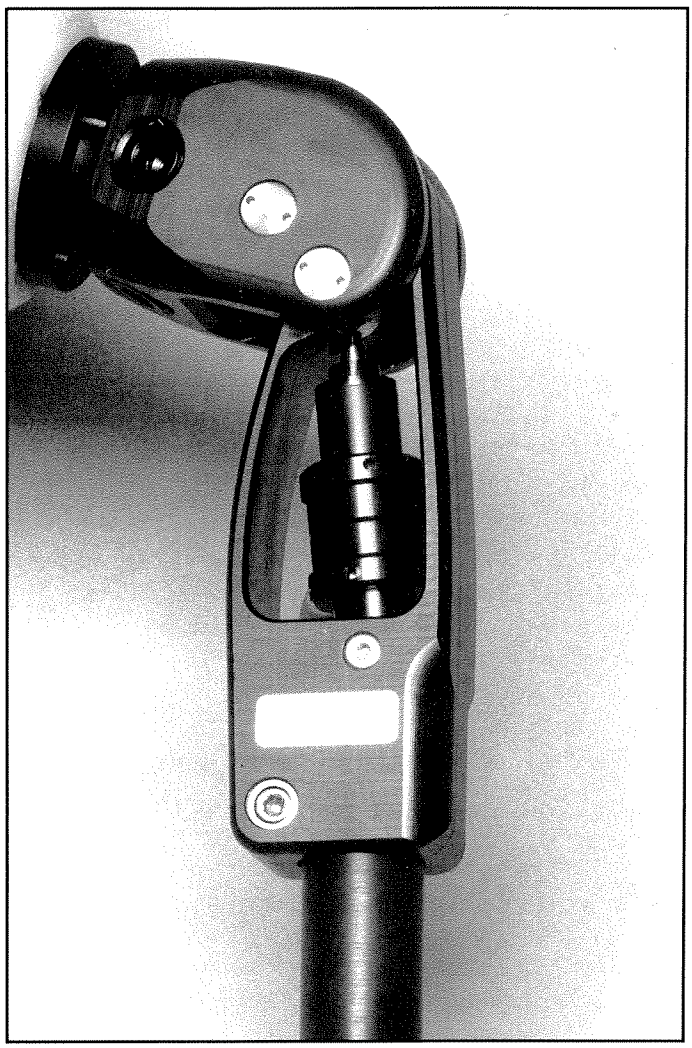

Figure 1.
Knee component of the DAV/Seattle Knee illustrating its being a dynamic structure that bends and straightens out.

Table 1.
Characteristics.

Weight (with fluid control unit)
20 oz. (570g)
4-5 lbs. (complete A/K SEATTLE Limb)
3 oz. fluid control unit
Dimensions
2.4 x 2.4″ proximal (1.5 x 2.5 distal)
9.3″ long including proximal alignment device
4.3″ from end of socket to front of bent knee when seated
Structure
Monolithic structure machine of nylon 6/6
Integral alignment proximal, ± 10° in all directions and unlimited rotation of knee axis
Stainless steel fasteners
Industry standard 30 mm shank receptacle distal
Industry standard 2 in. bolt circle attachment plate proximal
Swing phase dampening control from silicone fluid cylinder
Knee flexion range: 120° to a progressive stop and 150° total flexion with increasing elastic resistance

Figure 2.
Demonstration of the functionality of the DAV/Seattle Knee.

Function

The DAV/Seattle Knee and its variants are intended to be definitive knee components suitable for a broad range of amputee activity levels. Prosthetist-adjustable swing-phase dampening makes it easy to adjust the Knee to match the natural cadence of the amputee.

Greater mobility is achieved with the Knee because it allows the amputee to easily bring the hip muscle up (due to its light weight), and to bend the Knee easily because of little friction due to fewer parts (**Figure 2**). In addition to its light weight, the DAV/Seattle Knee is stable. When the amputee stands, the Knee straightens out because the center of gravity is at the front of the knee. This stops the Knee from buckling on the veteran.

CLINICAL EVALUATION METHODOLOGY

General

Thirty evaluation models were procured for this evaluation. The Chiefs, PSAS, who identified subjects for fitting, were designated as their local VA Medical Center's Participating Investigator (PI). The PIs' responsibilities were to coordinate and conduct the clinical evaluation of the DAV/Seattle Knee at their station. The PIs were given an evaluation protocol and data collection instruments to assist them in administering the clinical evaluation. The developer, Alan Aulie (Aulie Rehabilitation Devices, Inc.), was available by telephone to answer questions with regard to the fitting and use of the DAV/Seattle Knee. TTS and PSAS/VACO personnel provided constant communications throughout the evaluation period with field PIs to answer ongoing inquiries, provide technical support, and assist with problems.

During the initial phase of the clinical trials, two maintenance and repair data instruments were received. A common problem of the piston shaft ends breaking was identified. This was a fail-safe situation; the Knee support structure maintained its integrity and did not cause the subject to fall. All units were immediately returned to the manufacturer for installation of new damper mounts.

Evaluation Sites

With collaboration from the PSAS/VACO, TTS screened for potential participating field facilities. Selection was based upon acceptance of submitted candidates as appropriate subjects. Once facilities were identified, a letter was forwarded from the appropriate VA Regional Director, accompanied by the evaluation protocol and TTS 101K "Agreement to Participate." Field stations became participants of this evaluation upon the Program Manager, TTS's receipt of a completed TTS 101K "Agreement to Participate" and subsequent approval by the Research and Development Committee of the PI's VAMC (**Table 2**).

Subject Selection

The DAV/Seattle Knee is intended to be applicable for a broad range of trans-femoral amputees. Selection is limited for this study to veterans with an amputation level no longer than the juncture of the middle and distal thirds of the femur. Selection of amputees with a longer residual limb may cause the knee center of rotation to be located too low. Long trans-femoral and knee-disarticulation amputees require a modified design, still in the research phase.

Criteria for Screening Candidates

- Above-knee amputees successfully using a current prosthesis (the goal is to change the knee component only and not introduce other variables to confound the data)
- Weight of under 200 pounds
- Subject is cooperative and has a desire to participate and is available for fitting and follow-up
- Subject is not institutionalized and is engaged in ADL activities
- Subject is ambulatory (nonambulatory amputees are excluded in the interest of gaining as much insight as possible into the function of the Knee).

Table 2.
Participating Field Stations and Subjects Per Site.

Station	Subjects	Station	Subjects
Albany, NY	1	New York NY	2
Cleveland, OH	1	Seattle, WA	1
Phoenix, AZ	1	White City, OR	1
Richmond, VA	1		

Seven participating VA facilities and number of subjects that completed 30 day trials and submitted data to TTS.

LABORATORY TESTING

The DAV/Seattle Knee has successfully undergone performance testing in accordance with the ISPO "Philadelphia '76" structural standards. Specific tests performed were:

- Two separate 600,000 cycle tests with fluid control were performed December 1991. Knee bent to 90° at 44 cycles per minute. No detectable problems; 15,000 cycles with 200 lb. axial load forcing Knee into hyper-extension. No detectable problems.
- Knees tested to destruction. All Knees exceed the ISPO "Philadelphia '76" structural standards. All known failure modes are from "permanent elastic deformation" rather than from brittle failure (i.e., breakage).

The DAV/Seattle Knee has been evaluated by PRS including the fitting of 4 subjects who wore the Knee up to 4 months. Subject testing began May 24, 1991. Amputee subject testing has driven the clinical engineering phase of development. Rough prototypes were used by amputees in a controlled laboratory setting to identify design refinements. Additional refined prototypes were released for limited field testing on December 11, 1991. Field testing of the final prototype commenced in February 1992.

Fitting Instructions

No special fabrication methods, assembly, or fittings were required. The DAV/Seattle Knee is an endoskeletal device (**Figure 3**). Proximally, it attaches to the socket via industry standard four-bolt (2 inch-bolt circle) fixation. Distally, it attaches to a 30 mm pylon such as the rigid aluminum pylon from Otto Bock or to the nylon SEATTLE Ankle pylon. Alignment is adjusted by four set screws in a conventional way. Friction can be added, if desired, by the two outboard screws on the rear of the Knee.

Documentation and Data Collection

Clinical trials were projected to span one year of continuous use from the time the Knees were properly fitted and considered to be functional by the subject and prosthetist. Each subject was asked

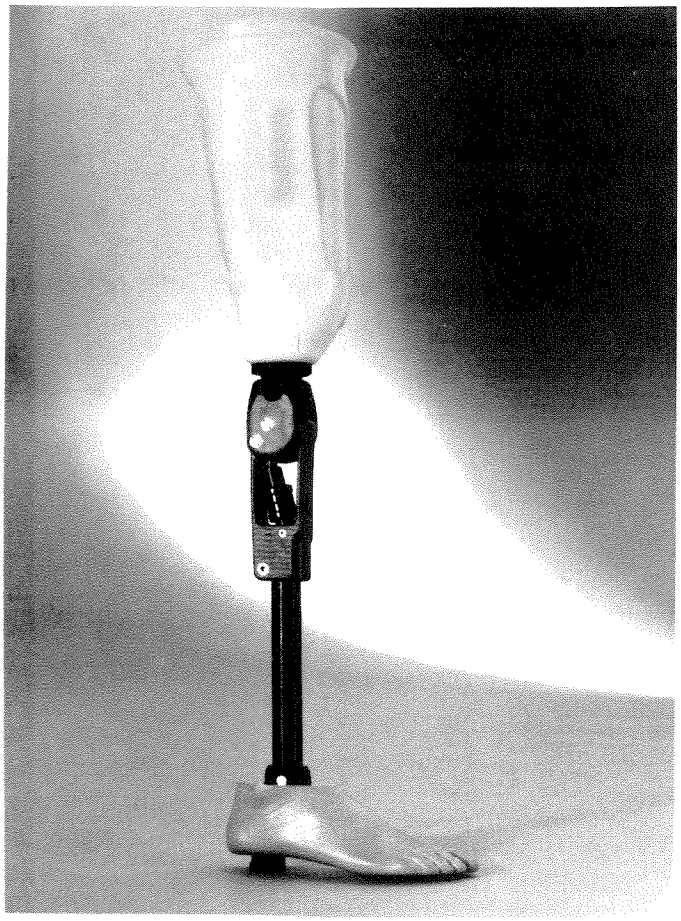

Figure 3.
DAV/Seattle Knee endoskeletal prosthesis.

to complete pre- and post-response data instruments assessing various aspects of prosthesis usage. Documentation of technical problems during clinical trials and repairs made by the manufacturer were to be completed on the maintenance and repair record and submitted immediately to TTS. All data instruments used in this evaluation were to be completed by the participating investigator by interview with the participants (e.g., subject, prosthetist, and therapist). An analysis of data for statistical measures and responses was tabulated (**Table 3**).

Table 3.
Data Instruments.

TTS 101	**Agreement to Participate**
TTS 102K	**Fitting** (Prosthetist's Response)
	Completed prior to fitting of evaluation model.
TTS 103K	**Subject's Background**
	Background information pertaining to subject.
	Subject's Evaluation Response
	PRE-completed prior to fitting of evaluation model.
	POST [30 Day]-completed after using the evaluation model for 30 days
TTS 104K	POST [90 Day]-completed after using the evaluation model for 90 days.
TTS 105K	**Maintenance & Repair Record**
	Completed if the device is damaged or broken.
Evaluation Summary	Completed by the PI and submitted to TTS after 30 and 90 day clinical trails for inclusion in interim and final reports.

RESULTS

Fifty-four candidates were screened to participate in the clinical evaluation of the DAV/Seattle Knee; 46 subjects met the subject selection criteria and were accepted into the study. Of the 46 subjects, 18 withdrew prior to fitting for various reasons (specialized equipment modifications required and lack of staff required to coordinate clinical trials). The remaining 28 subjects were fitted with the DAV/Seattle Knee. Of the 28 subjects, 23 completed the clinical trials for a minimum of 30 days; 5 withdrew prior to 30 days.

Of the 23 subjects that completed the evaluation for 30 days, 15 withdrew because they were dissatisfied with the performance of the Knee. As of September 1993, eight subjects were wearing the DAV/Seattle. TTS analyzed the data instruments for the 15 subjects and reviewed their reasons for withdrawal. Review by TTS indicated the following reasons for withdrawal: feelings of knee instability and buckling, inability to bend the knee properly, and slowness of the knee. These reasons were not clear or specific enough for drawing conclusions on the performance of the Knee. TTS telephone-interviewed some of the veterans who withdrew in order to find more conclusive reasons for rejecting the Knee. Most of the subjects that withdrew had been long-time successful wearers of the Otto Bock or the Mauch Stance-and-Swing-Phase Control hy-

draulic knees. Since these subjects were highly satisfied with their previous knee and, in retrospect, were probably not good candidates for this evaluation, the remaining data contained in this report will be based on the eight subjects currently wearing the Knee. The knowledge gained from the subjects who withdrew will contribute to the indications and contra-indications for future prescription of the Knee.

A synopsis of clinical findings, dated January 12, 1993, was prepared and distributed to appropriate parties. The report was accomplished to identify why the subject withdrawal rate was increasing at that time and if additional candidates should be recruited.

As of November 24, 1992, all units had been distributed to participating medical facilities for evaluation. The Installation and Fitting (TTS 102K) instrument had been received for all eight subjects. The fitting time ranged from less than 1 hour to 2 hours. Seventy-five percent of the prosthetists rated the fitting process as easy or routine (n = 8). Twenty-five percent of the subjects (n = 8) required training before they could walk comfortably with the Knee. Training time ranged from less than 1 hour to a maximum of 2 hours (**Table 4**).

An overall synopsis of the subjects' responses (n = 8) with regard to the performance and characteristics of the DAV/Seattle Knee was made from the data received and a review of comments made by the subjects and Participating Investigators. This report was based on eight subjects' evaluation of the DAV/Seattle Knee after 30 days of use (**Tables 5–7**).

Table 4.
Feature Rating.

Feature	Percentages	
	Satisfactory	Unsatisfactory
overall impression	87.5	12.5
appearance	87.5	12.5
knee center	100	—
standing balance	100	—
ability to ambulate at variable speeds	100	—

Prosthetist (n = 8) responses when asked to rate the features of the DAV/Seattle Knee.

Table 5.
Subject's Responses-Feature Rating (% of n = 8).

Feature	Percentages	
	Satisfactory	Unsatisfactory
overall (in general)	100	—
fit	100	—
appearance	75	25
standing balance	100	—
ability to ambulate at variable speeds	87.5	12.5
stability walking	87.5	12.5
stability standing	87.5	12.5
durability	87.5	12.5
function	87.5	12.5
comfort	100	—
weight	87.5	12.5
color	100	—
reliability	87.5	12.5
knee center	37.5	62.5

The opinions of the eight subjects during the 30 day clinical trials were used to aid in a determination of the acceptance or rejection of the DAV/Seattle Knee.

Advantages

- lightweight
- fit
- comfort
- appearance
- lower costs than other comparable knees on the market
- fewer moving parts (less maintenance and repair)
- durability
- corrosion proof
- allows 130° of flexion (for kneeling)

Disadvantage

- stance phase/control

Desired Changes

- simplify operation and adjustment of hydraulic unit

Table 6.
Gait Analysis (% of n = 8).

Characteristic	Helped	No Affect	Hindered	N/A
slow walk	62.5	37.5	—	—
regular walk	37.5	62.5	—	—
fast walk	37.5	25	12.5	25
jog/run	—	25	—	75

Table 7.
Knee Affect Gait (when going-% of n = 8).

Characteristic	Helped	No Affect	Hindered	N/A
uphill	25	62.5	12.5	—
downhill	12.5	75	12.5	—
up/down stairs	12.5	87.5	—	—
uneven terrain	37.5	62.5	—	—

- improve gait by quicker return of the shank
- increase friction
- include ability to install without increasing length and lower knee center (accommodate longer stump lengths to include knee disarticulations).

DISCUSSION AND CONCLUSION

TTS concluded from direct interview with subjects and prosthetists that the DAV/Seattle Knee is safe and reliable when properly matched to the user's weight, stump length, and activity requirements. Analysis of subjects' response indicated that the DAV/Seattle Knee did not respond adequately to different walking speeds, due to the shin section being slow, (prompting the subject to slow down for the Knee to catch up).

After a detailed analysis of subjects' responses, TTS discussed the problems encountered by the subjects with the developer/manufacturer. The developer has since added a friction adjustment to dampen heel rise evident between mid-stance to toe-off phases of gait to provide the desired level for the individual user. This adjustment effectively shortens the shin's movement by reducing toe-drop and limiting heel-rise, resulting in a quicker return of the shin section.

TTS also concluded, based on subject interviews and data analysis, that the high withdrawal rate was due primarily to the fact that these veterans were long-time successful wearers of other hydraulic knees and did not feel that the DAV/Seattle Knee functioned as well.

All eight subjects submitted evaluation responses after wearing the revised Knee for 30 days. Seven of the eight stated that they would like to continue using the DAV/Seattle Knee; while seven subjects indicated that they would purchase the Knee if it became commercially available. The remaining subject indicated that he would purchase the Knee if it were modified. In comparison to their previous knees, all subjects indicated that the DAV/Seattle Knee was the same or better.

The clinical trials confirmed that the DAV/Seattle Knee has the following advantages in comparison to similar hydraulic knee systems, it: 1) is lightweight; 2) is corrosion proof; 3) has very few moving parts; 4) allows 130 degrees of flexion at the Knee for kneeling; and, 5) is lower in cost.

The results of this evaluation demonstrate that the DAV/Seattle Knee can be prescribed for use by veteran beneficiaries; especially geriatric amputees who meet the prescription criteria (i.e., weigh under 200 lbs., have moderate ambulatory activity level, and any stump length except disarticulation; have no

contra-indications: persons who are successful wearers of the higher function knees currently on the market).

ACKNOWLEDGMENTS

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A special thanks to the developers, Ernest M. Burgess, MD, Director and Alan Aulie, Research Engineer, Prosthetics Research Study (PRS) Seattle WA, whose dedication, innovation, and caring contributed toward the development of a lightweight functional artificial knee that will provide persons with above-knee amputations, greater mobility than they have experience with other comparable man-made knees.

The Disabled American Veterans' Charitable Service Trust is highly commended for assisting in funding this research, development, and clinical initiative.

Appreciation is also extended to the PSAS Chiefs, and personnel, who performed as participating investigators soliciting test subjects, planning and conducting clinical trials, and monitoring the progress of evaluations.

Special recognition is directed to the following VA PIs: Robert Manion (Albany, NY), Elmer Bash (Cleveland, OH), John Milani and John Loosen (New York, NY), Ralph Eckard (Richmond, VA), Alan Langer and Diane Averbeck (Phoenix, AZ), Ronald Bailey and Martin McDowell (Seattle, WA), and Kevin Labarbara (White City, OR) who conducted complete and thorough clinical trials and submitted all of the required data. Subjects at their medical facilities are currently wearing the DAV/Seattle Knee.

Acknowledgment is gratefully extended to the most significant persons who accomplished the day-to-day necessities to make this study a reality, the TTS Staff: Vivian Taha, Estella Howard, and Laura Jennings. A special thanks is extended to Wijegupta Ellepola for his technical support in conducting a survey to determine the reasons for subject withdrawal.