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CLINICAL REPORT

Report on the Evaluation of the VA/SEATTLE Below-Knee Prosthesis

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Abstract—The Department of Veterans Affairs (VA), Rehabilitation Research and Development (Rehab R&D) Service, Technology Transfer Section (TTS) with collaboration from the Prosthetic and Sensory Aids Service (PSAS) managed clinical trials to evaluate the VA/Seattle Below-Knee (BK) Prosthetic System. The clinical trials were held at the Prosthetic Treatment Center (PTC), VA Medical Center, Hines, Illinois. Five other VA medical centers participated in the outreach program of the trials as satellite stations, with PTC Hines as the central fabrication facility. The VA/Seattle BK system is the first complete prosthetic system designed and developed by the Department of Veterans Affairs. It consists of a socket designed and fabricated using computer-aided, automated technology, and off-the-shelf modular components: a lightweight pylon and an ankle unit, and a lightweight, energy-storing foot. The computer-based socket design software, the modular components, and the prosthetic foot were developed with funds from the VA Rehab R&D Service. The evaluation trials were conducted to determine the efficacy of the VA/Seattle prosthesis, its reliability, and acceptance by veterans. The clinical trials began in April 1991 and were completed in August 1992. Forty-six BK amputee veterans were fitted with the VA/Seattle prosthesis. Their progress with the prosthesis was followed for a period of 6 months and data were gathered at intervals of 2 weeks, 3 months, and 6 months. Forty sets of subject data instruments were collected. In order to maintain the accuracy of the results, TTS used the 22 sets that were complete for data analysis.

The VA/Seattle below-knee prosthesis was well accepted by all the subjects participating in the evaluation trials and confirmed that it is comfortable to wear, safe and reliable. "Previous wearers" preferred it to their former prosthesis both in comfort and overall acceptability.

To optimize the technological advantages of the computerized prosthetic socket design and fabrication system, Automated Fabrication of Mobility Aids (AFMA), the VA should provide a complete and thorough orientation and training program to the VA prosthetists as it introduces the AFMA system into the Healthcare Delivery System.

Key words: *below-knee amputees, clinical evaluation, computer-aided design, computer-aided manufacturing, prosthesis.*

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INTRODUCTION

The methods of prosthesis design and fitting have remained relatively unchanged over the past 20–30 years, even though materials have changed. Traditional methods of prosthesis design, fabrica-

tion, and fitting are laborious and time-consuming. The mold of the residual limb taken for fabricating a prosthesis must be relieved over areas that cannot tolerate pressure, and decreased in areas over other strategic locations, to accommodate biomechanical considerations of gait. Such modifications are presently made by hand; several diagnostic sockets are fabricated using manual methods until a comfortable-fitting socket is achieved before a final prosthesis is fabricated. This artisan-like process is time-consuming, labor-intensive and expensive; therefore, it delays the timely delivery of prostheses to veterans. To improve timely delivery, the Department of Veterans Affairs (VA) Rehabilitation Research and Development (Rehab R&D) Service funded a long-term project to design and develop the VA/Seattle Below-Knee (BK) Prosthesis **Figure 1**. This new prosthetic system consists of a socket designed and fabricated using computer-aided design technology and interlocking, lightweight, modular components. This method of design, fabrication, and fitting of prostheses will enable the prosthetist to perform more fittings and improve the quality of care to the veteran.

The components of the VA/Seattle BK prosthesis were designed and developed by the Prosthetic Research Study (PRS), Seattle, Washington, with funds from the VA Rehab R&D Service. The computer-aided socket design and computer-aided manufacturing (CASD/CAM) system was tested and evaluated through a collaborative effort directed by Ernest Burgess, MD, between PRS, Seattle, WA; Prosthetics Research Laboratory, Northwestern University, Chicago, IL; and the Department of Rehabilitation Medicine, New York University Medical Center, New York, NY.

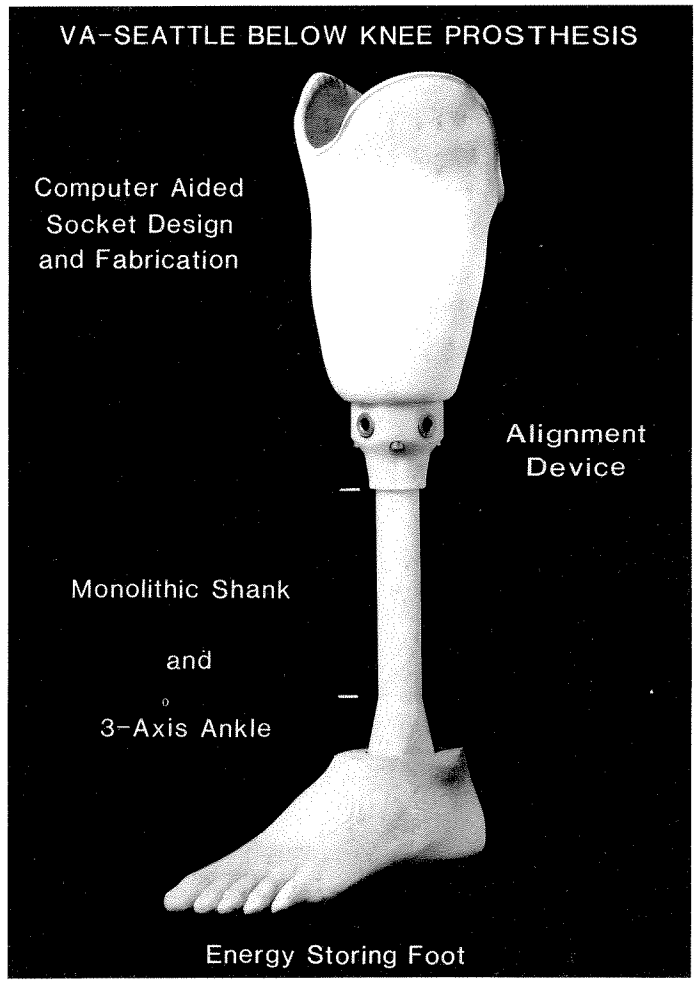

Figure 1.
The VA/Seattle Below-Knee Prosthesis.

PURPOSE

The purpose of this evaluation was to: 1) demonstrate that fabricating the VA/Seattle BK prosthesis using CASD/CAM technology is an efficacious, cost-effective plan for providing well-fitting prostheses to veterans in a timely manner; 2) provide an effective, expedient method to accommodate stump volume changes in cases of edema and/or residual limb tissue shrinkage; 3) provide a better system to manage immediate fittings of a prosthesis; 4) provide the capability to store modified "models" of successful fitting sockets in the computer for fabricating duplicate or new sockets without the need for storing plaster molds; 5) provide prosthetists, physicians, and therapists with quantitative, readily retrievable records of the physiological and anthropometric data of their patients; 6) ascertain whether it is safe and reliable; 7) determine patient acceptability; and, 8) facilitate the technology transfer of VA Rehab R&D funded research to clinical use.

DESCRIPTION

Function

The function of the VA/Seattle BK prosthesis is similar to other BK prosthetic systems. It differs by

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system integration in the method and technology used in the design and fabrication of the socket and the use of all plastic, modular components.

Physical Appearance

The VA/Seattle BK prosthesis consists of: a computer-designed, thermoformed socket; a lightweight, modular, plastic, socket attachment/alignment coupling; and, a one-piece, flexible shank/ankle. The shank/ankle is capable of providing 10–15 degrees of ankle dorsi/plantar flexion, and 2 degrees of axial rotation. The prosthesis is complete with a lightweight, energy-storing foot and weighs between 2 and one-half to 3 pounds.

METHODS

Evaluation Sites

Prosthetic Treatment Centers at VA Medical Centers (VAMCs) Hines, Milwaukee, Kansas City, Minneapolis, and Louisville participated in the clinical evaluation trials. Hines was the designated central fabrication site for the "outreach" program.

Subject Selection

Unilateral or bilateral BK amputees prescribed by a physician to receive a patellar-tendon-bearing BK prosthesis with cuff suspension, soft-liner (Pelite), and a Seattle Light Foot were selected to participate in the evaluation trials. The subjects were required to be reasonably active, alert, cooperative, and willing to participate in the trials. Candidates with significant clinical problems such as ulcers, difficult neuromas, etc., in the residual limb, were excluded from this evaluation.

Laboratory Testing

Since the socket design and fabrication system and the modular components were previously evaluated independently and demonstrated to be reliable and safe, the Technology Transfer Section (TTS) determined that cyclic laboratory tests to document durability and reliability over long-term usage of each component of the VA/Seattle prosthesis was not necessary.

Prosthesis Fittings

Anatomical measurements, physical characteristics of the residual limbs, ranges of motion of the knee joint, physical activity, and previous prosthesis use were obtained from the subjects. An unmodified plaster of Paris wrap cast of the residual limb was taken during the subjects' initial visits to the clinic. The plaster wrap casts were digitized and prosthetic sockets were designed using ShapeMaker socket design computer software. Diagnostic sockets were fabricated on a replica model of the residual limb using the computer-aided, automated process and fitted on subjects to determine the accuracy of fit. Prosthetists were allowed to fabricate and fit a maximum of six diagnostic sockets to optimize socket fit.

The complete prosthesis was assembled using the modular components after obtaining a well-fitting socket. The prosthesis was then dynamically aligned for each subject for optimum gait. Established standards of alignment criteria were followed during static and dynamic alignment of the prosthesis. Subjects were instructed in gait training and the proper use of their prostheses. They were evaluated at 2-week, 3-month, and 6-month intervals. Data regarding the subject's experience with the prosthesis were collected at each visit.

The satellite sites in the outreach program selected the candidates, casted the residual limbs, and then sent the casts to Hines VAMC for socket fabrication and assembly of the prosthesis. Satellite stations collected the same data as Hines and the data were provided to TTS. The subjects were allowed to keep the prostheses they had received during the evaluation trials and have since chosen to use them as their permanent prosthesis.

Documentation and Data Collection

Data regarding each subject's experience with the prosthesis and the delivery system were collected using the following data instruments: Subject's Background and Initial (pre-fitting); 2 weeks, 3 months, and 6 months post-fitting; and Prosthetist-Initial and 3 months post-fitting.

RESULTS

A total of 46 subjects were fitted with VA/Seattle BK prostheses during the clinical trials. PTC, Hines (the lead center), fitted 28 subjects and the outreach satellite clinics fitted 18. Of the 46 subjects fitted, 22 fully participated in the study and

provided complete sets of data instruments to TTS; 11 did not provide complete data sets, and 13 withdrew for medical and other reasons not related to the evaluation trials. Four of the 18 subjects fitted at the satellite clinics provided complete sets of data instruments.

All 46 subjects in the trials were males and were mostly World War II veterans. Eighty-five percent of the amputations were non-service-connected; 15 percent were service-connected. Sixty-two percent of the subjects were above the age of 60 years; the youngest was 41, and the oldest was 83 years old. Fifty-two percent had left-leg amputations, 46 percent had right-leg amputations, and 2 percent were bilateral amputees. Forty-three and one-half percent of the subjects were amputated due to diabetes; 30.4 percent due to peripheral vascular disease (other than diabetes); 8.7 percent due to trauma; 2.2 percent due to cardiovascular disease; and 15.2 percent for other reasons (**Figure 2**). Forty-three percent of the amputations due to diabetes were performed in 1991.

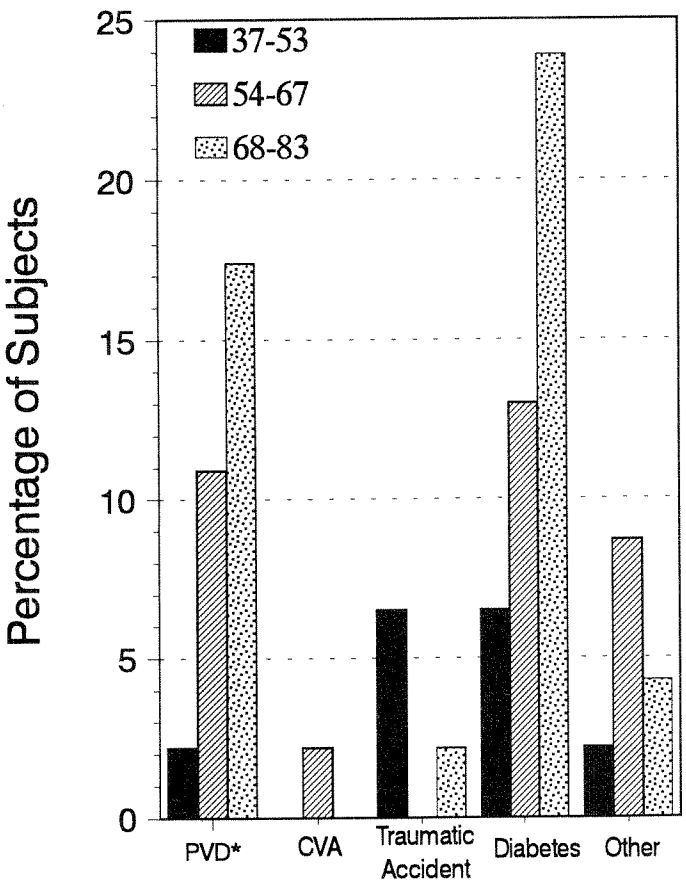

Figure 2.
Subject's Age/Cause of Amputation (other than diabetes).

Ninety-five and one-half percent of the 46 subjects identified walking as the primary reason for needing a prosthesis, and 4.5 percent indicated standing as the second most important function. Running was consistently chosen as a low priority by all subjects; it is assumed that the advanced ages of the subjects in the clinical trials might account for this low rating.

In order to compare the attributes of the VA/Seattle prosthesis with that of other BK prostheses, the 46 subjects in the trials were classified into two groups: subjects who had never worn a prosthesis previous to the evaluation trials were identified as "new wearers," and subjects who had been wearing a prosthesis at the time of the trials were identified as "previous wearers." According to these categories, 63 percent of the subjects were new wearers and 37 percent were previous wearers. The previous wearers, at their initial visit to the evaluation clinic, rated the quality of fit and comfort of their previous prosthesis according to a set of preselected attributes. At the end of 6 months of using the VA/Seattle prosthesis, both new wearers and previous wearers rated the VA/Seattle prosthesis according to the same above set of attributes.

Of the 46 subjects fitted with the VA/Seattle prosthesis, 22 fully participated in the 6-month evaluation trial period. The results reported are therefore based on the data instruments from these 22 subjects and are described in **Figure 3** through **Figure 6**. In rating the "satisfaction" with the VA/Seattle prosthesis, 100 percent of the 22 subjects said they were satisfied. In contrast, 65 percent of the 17 previous wearers, prior to receiving the VA/Seattle prosthesis, said that they were satisfied with their previous prosthesis, 29 percent were dissatisfied, and 6 percent had no opinion (**Figure 3**).

Ninety-five and one-half percent of the subjects said the fit of the VA/Seattle prosthesis socket was "very good" and 4.5 percent said it was "good" (**Figure 4**). In contrast, 41 percent of the previous wearers rated the fit of their previous prosthetic socket as very good, 18 percent good, 17 percent adequate, 12 percent poor and very poor, respectively (**Figure 5**).

Ninety-one percent selected the quality of suspension of the VA/Seattle prosthesis to be very

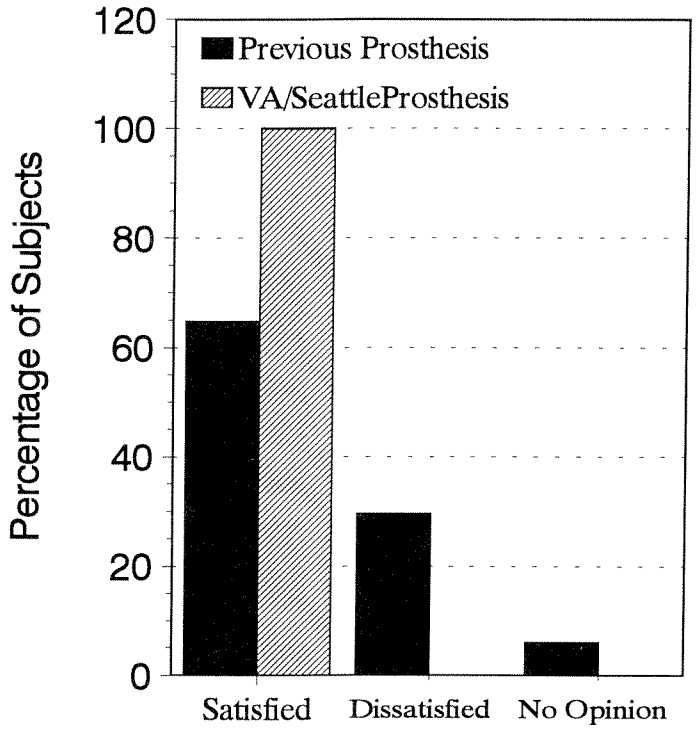

Figure 3.
Prosthesis Satisfaction Rating.

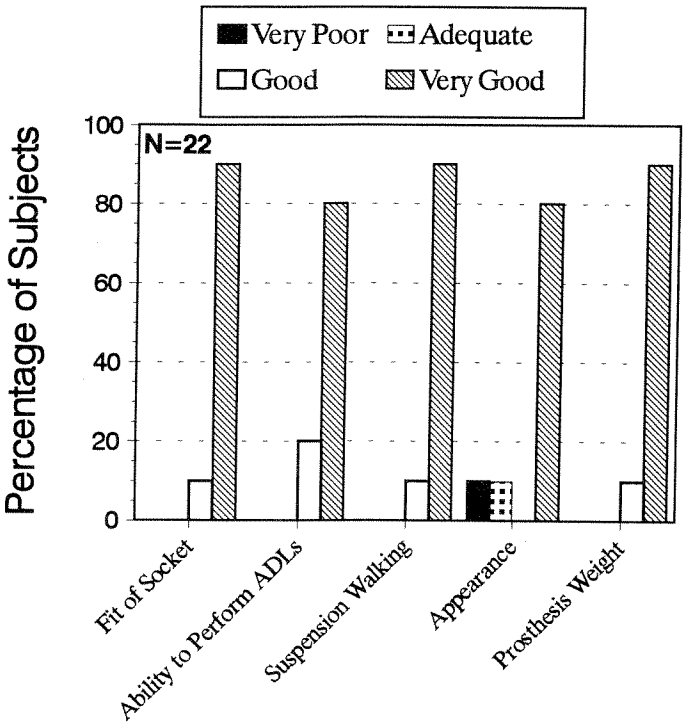

Figure 4.
Features of VA/Seattle Prosthesis.

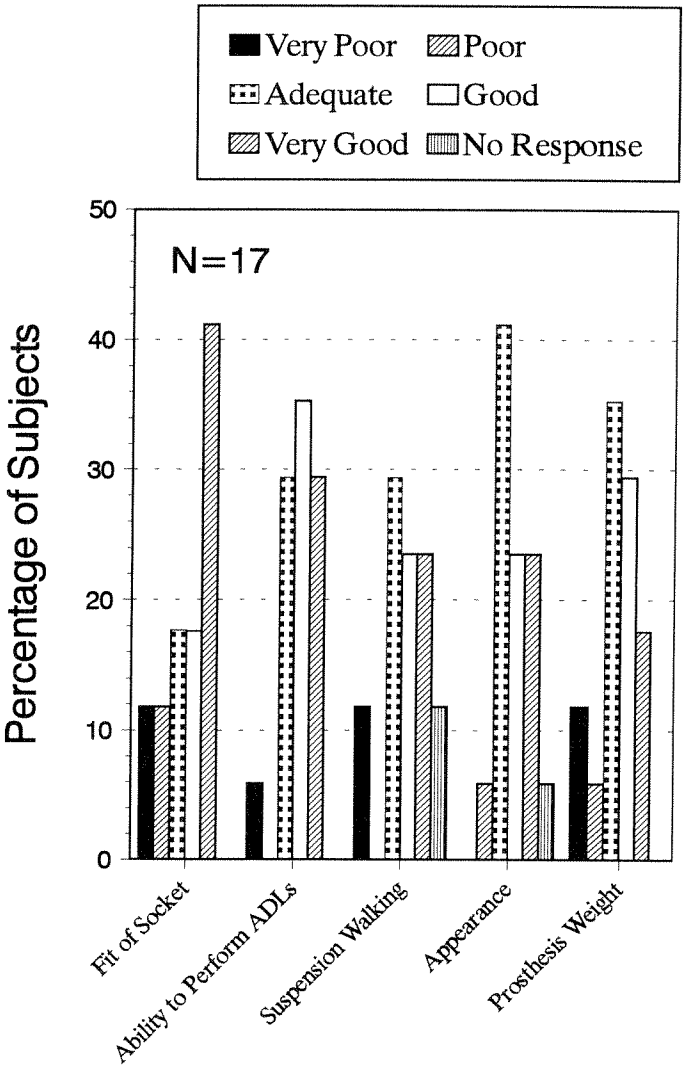

Figure 5.
Features of Previous Prosthesis.

good and the remaining 9 percent rated it as adequate. In comparison, only 23.5 percent of the previous wearers felt that their previous prosthesis suspension was very good, 23.5 percent rated them as good, 29 percent as adequate, and 12 percent as very poor; 12 percent had no response (**Figure 5**).

Ninety percent of the 22 subjects considered the weight of the VA/Seattle prosthesis to be very good and 10 percent said it was good (**Figure 4**). Rating the same attribute, 18 percent of the 17 previous wearers rated the weight of the previous prosthesis as very good, 29 percent as good, 35 percent as adequate, 6 percent as poor, and 12 percent as very poor (**Figure 5**).

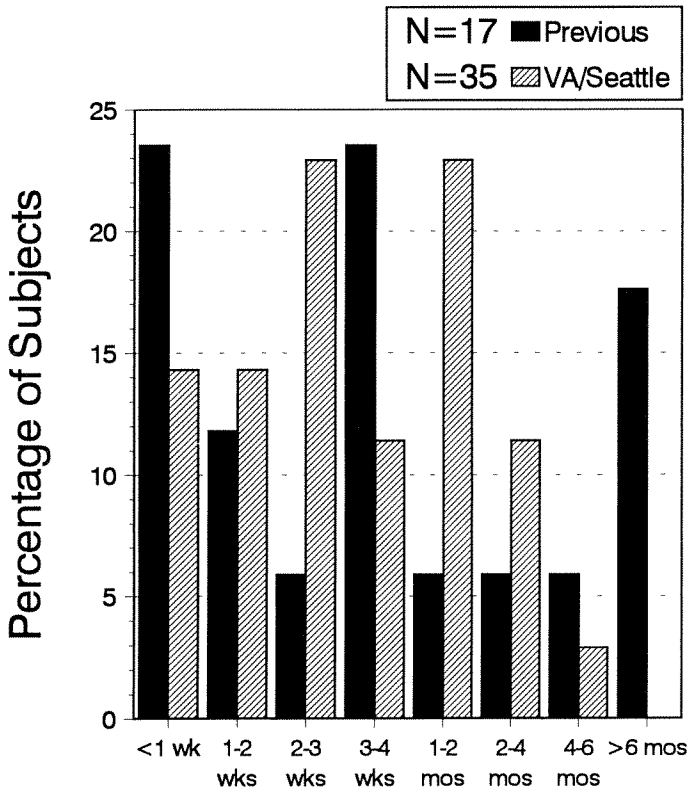

Figure 6.
Time Casting and Receiving Prosthesis.

Eighty percent of the 22 subjects agreed that their ability to perform activities of daily living (ADL) was very good with the VA/Seattle prosthesis, while only 29 percent of the previous wearers considered the same to be true with their previous prosthesis.

One of the important goals of the evaluation trials was to verify the claim that the VA/Seattle prosthesis could be delivered to a patient "sooner" than conventional practice. To determine this, TTS collected subjects' recollections of the casting and delivery dates of the previous prosthesis from the 17 previous wearers, and compared them with those of the 35 subjects who received a VA/Seattle prosthesis. The comparison was made of 35 subjects, because records of 11 out of the 46 subjects fitted with the VA/Seattle BK prosthesis were not available to TTS.

Analysis of the data from the 17 previous wearers revealed that 23 percent of the subjects received their prosthesis in less than 1 week, 12 percent received theirs in from 1 to 2 weeks, 6 percent from 2 to 3 weeks, 23 percent from 3 to 4 weeks, 6 percent from 1 to 2 months, 12 percent from 2 to 6 months, and 18 percent waited longer than 6 months. In comparison, 14 percent of the 35 subjects received their VA/Seattle prosthesis in less than 1 week, 14 percent in from 1 to 2 weeks, 23 percent from 2 to 3 weeks, 11 percent from 3 to 4 weeks, 23 percent from 1 to 2 months, and 15 percent from 2 to 6 months (**Figure 6**). These results indicate that the prosthesis delivery time did not improve during the evaluation trials using the VA/Seattle prosthesis. The percentage of subjects who received their previous prosthesis in less than 1 week decreased by approximately 50 percent in the clinical trials using the VA/Seattle prosthesis. In contrast, the 3- to 4-week group using the VA/Seattle prosthesis improved by nearly 50 percent.

DISCUSSION

The clinical evaluation trials were designed to determine the acceptability of the VA/Seattle prosthesis by BK amputees and to demonstrate its safety, reliability, and efficacy as a cost-effective plan for providing well-fitting prosthesis to veterans.

The evaluation results clearly indicated that this prosthesis was well accepted by all of the subjects who fully participated in the trials and that it was comfortable to wear. It was confirmed that due to its having fewer parts, the VA/Seattle prosthesis is easy to assemble, adjust, service, and replace, and requires less maintenance.

The results indicated that although the computer-aided technology and modular components allowed for quicker fabrication of sockets and assembly of a prosthesis, the actual delivery time of a prosthesis was not reduced. Previous studies clearly proved that the use of computer technology for designing and fabricating a prosthesis did improve the delivery time by reducing the time between casting and delivery of the final prosthesis. Therefore, the VA/Seattle prosthesis evaluation findings point out the critical need for education and training of staff using the new technology in order to maximize its use for improving the prosthesis delivery time to veterans.

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CONCLUSIONS

The VA/Seattle BK prosthesis was well accepted by all subjects participating in the evaluation trials and the users confirmed that it is comfortable to wear, safe, and reliable. Previous wearers preferred it to their former prosthesis both in comfort and overall acceptability. To optimize the technological advantages of the CASD/CAM system for automated fabrication of mobility aids (AFMA), the VA should provide a complete and thorough orientation and training program to the VA prosthetists as it introduces the AFMA system to the Healthcare Delivery System.

AVAILABILITY

All components of the VA/Seattle prosthesis are commercially available. Veterans interested in being fitted with a VA/Seattle BK prosthesis are encouraged to contact the Chief, Prosthetic and Sensory Aid Service (PSAS) at their local VA Medical Center.

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