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CLINICAL REPORT

Clinical Evaluation of a New, Above-Elbow, Body-Powered Prosthetic Arm: A Final Report

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Abstract--The AdVAntage Arm^{TM} is an above-elbow (AE) body-powered arm designed to improve upon, and overcome, some of the major limitations of conventional prostheses. It is the result of research and development (R&D) accomplished at the Center for Engineering Design (CED), University of Utah and Sarcos Research Corporation (SRC), Salt Lake City, UT. The AdVAntage Arm was developed to provide the following main features: lightweight, independent elbow and terminal device (TD) control, and a cable recovery system for full TD actuation at any elbow position.

The Department of Veterans Affairs (VA) Rehab R&D Service's Technology Transfer Section (TTS), with collaboration from the VA National Prosthetic and Sensory Aids Service (PSAS), managed a multi-center clinical evaluation of the precommercial AdVAntage Arm (the Arm). The purpose was to objectively assess and affirm the Arm's functional advantages, reliability, clinical application, and commercial readiness.

Eleven VA prosthetic services served as evaluation sites with a total of 16 subjects with amputation (14 unilateral and 2 bilateral). Fifteen prosthetists provided their comments. Overall, the results demonstrated that the Arm could be fit for use by persons with transhumeral amputation. Once the learning curve was overcome, the majority of subjects reported that the Arm offered several functional advantages over their

conventional prosthesis. Its overall lightweight, separation of elbow and TD function, and cable recovery system allowed opening and closure of the TD at any elbow position; resulting in a more fluid manner of use and allowing subjects to perform more activities from waist level and above (especially in the outstretched and overhead positions). At the conclusion of clinical trials, 10 subjects elected to keep the Arm for continued use.

The manufacturer is committed to the commercial marketing and technical support of the arm. Based upon the clinical findings, the AdVAntage Arm was recommended for commercial production and availability, upon prescription, to appropriate veteran beneficiaries.

Key words:above-elbow, AdVAntage Arm, amputation, body-powered, clinical evaluation, prosthesis, technology transfer, transhumeral amputation.

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INTRODUCTION

One of the high priority areas for the Department of Veterans Affairs (VA), Rehabilitation Research and Development (Rehab R&D) Service involves prosthetics, amputations, and orthotics. The VA supports research and development that result in artificial limbs that are lighter, better fitting, and permit more natural movement for activities of daily living (ADL).

In 1985, LeBlanc (1) stated, "Standard body-powered upper-limb prostheses have not changed significantly since developments in the 1950s [that] were spurred by World War II. [Prosthetists] still employ ancient technology using a shoulder harness and steel cables for operation." This observation still holds true today. The artificial arm problem has not yet been solved. "Adequate replacement of the human hand and arm is one of the most difficult problems facing medical technology" (2). Only 50 percent of those with upper limb amputation are estimated to wear prostheses, versus 75 percent for persons in need of lower limb prostheses (3). In part, this is because the loss of one leg is far more debilitating in the process of ambulation than the loss of one arm is in manipulation. However, the statistics also indicate a general dissatisfaction with upper limb prostheses. Many individuals with upper limb amputation (particularly those with one sound arm) feel that a prosthesis offers too little cosmetic benefit or functional advantage to compensate for the discomfort and inconvenience of wearing the device (4).

Although the use of externally powered prostheses is increasing, current estimates are that 90 percent of individuals who wear upper limb prostheses use the body-powered

types because they are relatively inexpensive, functional, reliable, and have some sensory proprioceptive feedback from the shoulder harness and cable control system (5). Even with these relative benefits, "to actually move the elbow, large forces are required due to the 'mechanical disadvantage' experienced by the shoulders. Because of these high forces, lifting ability is extremely limited" (4). Studies at New York University indicate that it requires 5.08 cm of excursion to flex the elbow to full flexion and 6.35 cm of excursion to open the terminal device (TD) fully at the mouth. Therefore, a total of 11.43 cm of excursion is necessary to fully operate a traditional above-elbow (AE) prosthesis (6). A drawback of conventional AE prostheses is that the same cable is used for both the elbow and TD. This requires extra motion of the cable in order to actuate the TD when the elbow is fully flexed. The shorter the length of the humerus, the more difficult it is to develop excursion of the cable and, therefore, the more difficult to perform activities that occur with the elbow flexed and the TD open, usually near the wearer's midline or mouth. Although full TD opening is not a goal of most individuals with unilateral transhumeral amputation (THA), it remains a goal for many of them, even though they still have one normal hand. Persons with short AE amputations have difficulties performing full TD opening near the mouth (6).

The higher the level of amputation, the more difficult it is for the person to control the functions of the limb. For those with THA, more exertion and greater gross body motion are required to operate an elbow plus a terminal device (7). *Weight reduction in upper limbs is extremely important and may be the difference in a person's decision to wear or not wear an artificial arm.* The constant axilla pressure creates a fair amount of discomfort. This pressure is directly related to the weight of the total prosthesis. For the person with lower limb amputation, the weight can be relieved while standing, sitting, and even walking, but the person with upper limb amputation is frequently saddled with a constant hang weight (8). The combination of high popularity with significant problems gives the impression that the body-powered prosthesis has functional advantages that have been overlooked (4).

The AdVAntage Arm^{TM} (**Figure 1**) is designed to improve upon, and overcome, some of the major limitations of existing body-powered arms. It is the result of research and development (R&D) accomplished at the Center for Engineering Design (CED), University of Utah, Salt Lake City, UT and Sarcos Research Corporation (SRC), Salt Lake City. The CED also developed the Utah Arm, which is still the most advanced commercially available myoelectric prosthesis (9).

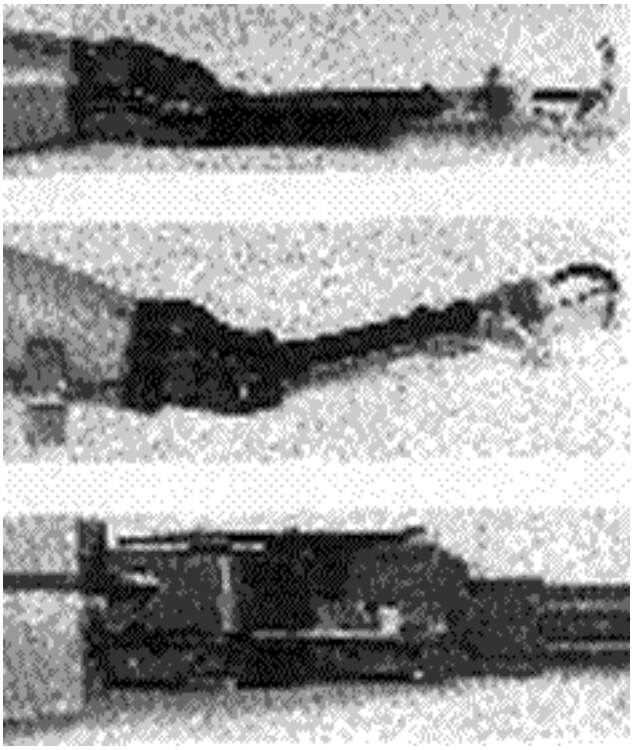

Figure 1. Several views of the AdVAntage Arm.

The CED and SRC (the manufacturer), based upon design criteria from the 1989 VA Prosthetics/Orthotics/Amputations Priority Workshop that called for "body-powered elbows that provide greater range of motion (ROM), and adjustable force excursion requirements," developed the AdVAntage Arm (the Arm) to provide these features and several more. These new milestones in prosthetic technology have been enabled by the application of advanced computer-aided design (Pro-E) and composite injection molding techniques; which led to efficient mechanical computations and control functions, and the design of the new lightweight, body-powered Arm. Developers felt that these unique design features would make the Arm especially useful for persons with high-level THA (**Figure 2**), bilateral amputation, and those with limited shoulder motion.

Figure 2. Subject with a short transhumeral amputation level using the AdVAntage Arm. High elbow flexion angle allows full operation of TD at and around the mouth and head area.

The AdVAntage Arm has the following claimed advantages over existing, conventional body-powered systems:

- It has independent elbow and TD control
- It is lightweight--460 gms (elbow and forearm structure)
- A spring-powered, cable recovery system for full TD actuation at any elbow position (i.e., TD is fully functional for activities from midline to mouth and head area)
- It has reduced cable pull for improved lift gain/assist
- It uses Spectra 1000® cable for internal TD cable routing
- It has adjustable forearm length
- It has a front elbow hinge for high flexion angle: 20°-148° (conventional elbow range is 0°-135°)
- it has a lift assist for gravity compensation and improved elbow flexion and lift.

This R&D effort led to the submittal of a Request for Evaluation (RFE) to the VA Rehab R&D's Technology Transfer Section (TTS) for review. Results of the peer reviews were positive and endorsed proceeding with a national, multi-center clinical evaluation. TTS coordinated the evaluation of the precommercial Arm as part of the technology transfer process.

During the initial process of transferring this precommercial arm, many unforeseen design changes surfaced. Technical problems arose when attempting to fit the first five arms. Subjects were unable to achieve a functional level of acceptance in order for clinical trials to commence. This necessitated a hold on further manufacture and a recall was initiated by the manufacturer to reevaluate and incorporate design improvements. Subsequently, the following changes were made: relocation of the control mechanism from the forearm assembly to the elbow and the addition of a wrist interface that would accept the most commonly used TD. As a result, manufacture and clinical trials of the remaining 15 arms, with the revisions, was resumed.

The purpose of the evaluation was to determine the acceptance of the precommercial Arm by the target population; assess its potential for improving functional levels of independence for the intended user; validate the effectiveness of the design features; and identify any modifications that might be needed to improve optimal clinical use and enhance its marketability. Specific areas to be scrutinized in this evaluation were:

- Prescription guidelines and target population
- Fitting requirements (i.e., determine if the prosthesis can be fit by local prosthetists using existing techniques)
- Training requirements
- Instructional materials (i.e., supplied manuals were evaluated for clarity, effectiveness, and completeness)
- User acceptability in terms of ease of operation, functional advantages, and cosmesis
- Improved function and utility over conventional body-powered AE prostheses
- Reliability and effectiveness of design features
- Commercial readiness.

DESCRIPTION

The Arm is an AE body-powered prosthesis designed to offer a unique separation of the elbow movement mechanism from TD actuation, which allows opening and closure of the TD at any elbow position using the same cable excursion. Functional characteristics are detailed in **Table 1.**

Table 1.
AdVAntage Arm^{TM}: functional characteristics.

Characteristic	Numerical Range
Excursion Range	128° (20° to 148° elbow flexion)
Angle past horizontal	58°
Main cable travel	2 in
Lock/unlock cable travel	3/8 in
Total weight: (elbow and forearm assembly	460 g
Life lock positions	9
Active lift/Load limit (locked)	2.5 lbs/50 lbs

When the elbow is controlled, the TD is disconnected from the control cable. When the TD is controlled, the elbow is locked and disconnected from the control cable. There is cable recovery when the state is changed so that the total required cable excursion, in order to fully flex the elbow and fully operate the TD, is reduced over that of conventional prostheses.

Control is by conventionally positioned dual cables. The control cable drives the elbow and TD sequentially according to the state of the switching mechanism. The lock cable locks the elbow and simultaneously changes the state from elbow control to TD control. The system consists of two main parts, the elbow mechanism and forearm structure. The elbow contains the mechanism that controls the function of the arm and the state changer lock pin lift assist. A sequential pull of the lock cable will unlock the elbow and change the state from TD to elbow control. Polymer cable material (Spectra 1000®) is used for both the control and lock cables. This material provides very low friction as well as high strength.

The Arm uses a standard socket and a conventional dual cable harnessing system, such as the figure-eight harness, for attachment and actuation. For correct operation of the cable recovery system and state changer, the harness must be adjusted so the wearer is able to relax the actuation cable. Operation of the Arm is similar to typical dual cable control systems, with one exception. After a lock or unlock command, the wearer relaxes the actuation cable to allow the logic cable to engage the state changer device. For example, if the Arm is raised to a position and locked, the actuation cable must be relaxed until the TD is engaged. Pulling on the actuation cable will then operate the TD. Pulling on the lock cable again to unlock the Arm will release the TD control but will not unlock the elbow until the actuation cable is pulled to the appropriate position to engage the elbow control. The elbow will unlock at that point and the actuation cable will control the elbow motion once again.

CLINICAL EVALUATION METHODS

Evaluation Models

TTS contracted and procured 20 precommercial models of the Arm for evaluation purposes (SRS, Salt Lake City, UT).

Subject Selection

With collaboration from the Chief Consultant, Prosthetic and Sensory Aids Service (PSAS), VA Headquarters (HQ), TTS coordinated the subject selection for the clinical evaluation of the Arm. The following subject selection criteria, as provided by the developer, was transmitted to Chiefs, PSAS, VA-wide:

Primary Indications

- Uses a conventional, dual cable control, AE prosthesis
- Unilateral or bilateral amputation.

Supplemental Indications

- Unable to use or has marginal use of a conventional prosthesis due to high-level amputation and limited cable excursion.

Primary Subject Characteristics

- Cooperative and willing to participate
- Available for follow-up
- Ambulatory and active
- Employment preferred.

Data instruments were completed on each potential subject assessing their current physical and prosthetic function. These data were reviewed for approval by PSAS (VA HQ)/TTS/CED/SRS to ensure that the intended subject fully met the stated criteria. Upon approval, a memorandum, acknowledging participation in the evaluation and concomitant responsibilities, was sent from the appropriate Regional Director to the Director of the VA Medical Center (VAMC) responsible for the subject's prosthetic services.

All approved subjects received information on the purpose and significance of their participation in this evaluation. Each was informed that participation would involve a 30- and 90-day follow-up visit after the fitting was complete. Informed consent was obtained from each subject prior to their fitting and in accordance with the respective VAMCs.

Fitting Process

The costs for fitting the revised Arm were covered by PSAS VA HQ. The fitting site supplied the wrist and TD. Preferably, these were the same as the subject was currently using. The local prosthetist fabricated the socket and harness; the socket was conventional. The harness was also conventional, with modifications, as needed, to ensure rotational stability, since the control cable must be able to be relaxed by the wearer.

A User's Manual was supplied with each elbow unit. The manual included operating and fitting instructions and a prosthetic checkout for the Arm. According to the manual, a manufacturer's technical liaison was designated as point of contact for questions pertaining to the fitting process and for any technical issues that arose during the evaluation.

Training

An outline for training procedures was provided by the developer and included as part of the protocol.

Maintenance and Repair

In the event of arm malfunction, the designated field Participating Investigator (PI) was instructed, in the protocol, to document (TTS-105 data instrument) the incident and submit the form to the Project Manager, TTS.

Documentation and Data Management

All data instruments, used for this evaluation, were completed by the field PI at each center via interview with evaluation participants (i.e., subjects, prosthetist, and therapist). Data analyses for statistical measures and responses were tabulated using the Statistical Package for the Social Sciences (SPSS/PC+).

RESULTS

The following results are based upon data collected from the participating subjects, prosthetists, and field PIs. Sixteen subjects met the criteria and were accepted into the study; all subjects completed pre-fitting data instruments. Fifteen of the 16 completed the 30-day post-fitting instruments. One subject was lost to follow-up. Eleven subjects completed the 90-day post-fitting instruments. Of the 5 subjects who terminated their clinical trial at the end of their 30-day follow-up, 4 reported that it was primarily due to their inability to function properly with the Arm. A fifth subject was unexpectedly hospitalized. Fifteen out of 16 prosthetists completed fitting instruments.

Subject Characteristics

The subject characteristics (as shown in **Table 2**) are based on the completed Subject Background data instruments. (Two of the approved subjects had bilateral THA).

Table 2.

Subject sample.

Characteristics	N=16	%
Age Groups	31-45	19
	46-60	44
	61-75	31
	75+	6
Sex	Male	94
	Female	6
Presently Employed	Yes	50
	No	50
Type of Employment (n=8)	Administrative	37
	Clerical	13
	Technical	13
	Other	37
Amputation Type	Unilateral	88
	Bilateral	12
Amputation Levels (n=18)	Forequarter	6
(two subjects are bilateral)	Short AE	39
	Standard AE	55
Years Post-Amputation (n=18)	1-5	16
(two subjects are bilateral)	5-10	6
	10+	78

The subject sample was a very diverse group, with geographic location distributed throughout the country. Subjects resided in a variety of environments from rural to urban

settings. They ranged from extremely active, heavy-duty users to those who would be considered light-duty users. A majority of the subjects were long-time prosthetic wearers. This diversity provided for a very comprehensive clinical trial. All subjects were very motivated to participate and were looking forward to trying a more functional and efficient body-powered arm.

Nineteen percent of the subjects reported poor strength and ROM of the residual limb. These subjects had experienced difficulty with conventional body-powered arms and were considered good candidates for the Arm based upon its unique cable recovery system and lightweight features.

Fifty percent of the subjects indicated usage of modifications such as an axilla loop, shoulder sling with axilla loop, or excursion amplifier to increase dual control function of their existing body-powered arms.

Eighty percent of the subjects employed shoulder extension on the amputation side to control their elbow lock while the remaining used shoulder flexion on intact side and manual pull with the intact hand.

Of the 16 subjects, 75 percent utilized an exoskeletal prosthesis while the remaining 25 percent reported using an endoskeletal.

Subject Response (Pre-AdVAntage Arm)

Prior to receiving the Arm, each subject completed a Subject Response (PRE) data instrument. The data gathered from this instrument is based upon the subject's, present or past, prosthetic experiences and provided comparative data for the Arm.

A majority of subjects (88 percent) used their present arm for more than 5 hours per day and between 5-7 days per week (88 percent). Subjects rated features of their present arm as shown in **Table 3.**

Table 3.

Subject's rating of features of present prosthesis (N=16).

FEATURES	% POOR	% FAIR	% GOOD	% EXCELLENT	% N/A
Elbow control	25	25	50		
Terminal device control	20	37	37	6	
Cable control system	19	44	31	6	

Ease of use	6	50	30	6	
Reliability	19	12	56	13	
Forearm lift	50	13	31		6
Cosmesis	13	56	31		
Noise level	6	37	57		
Weight	12	38	44	6	
Training	12	38	44	6	
Durability	6	12	69	13	
Donning/Doffing	6	31	38	19	6
Suspension system	6	31	56	7	
Comfort	19	38	37	6	

Each subject experienced some malfunction with his/her prosthesis and in some cases found the length of downtime to be unacceptable.

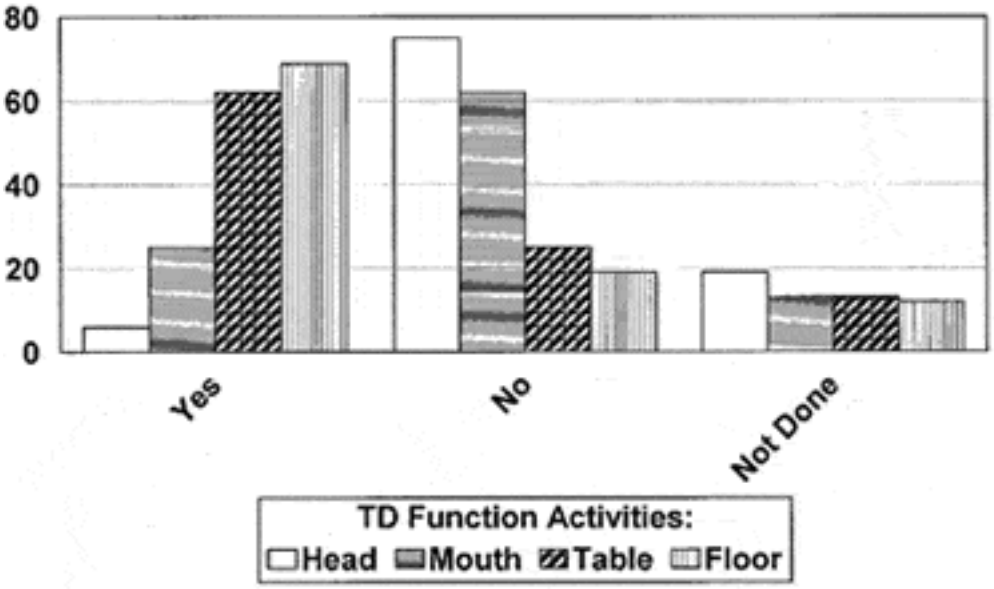

Figure 3. *Subject's rating of TD function of present prosthesis (N=16).*

Figure 3 focuses on subjects' rating of TD function for specific activities. For any item rated *No* or *Not Done*, the following comments were provided:

1. "Unable to voluntarily open the TD due to suspension and control cables when elbow is flexed."
2. "My prosthesis is not very functional."
3. "Not enough cable."
4. "Unable to open TD when arm is flexed, also locked elbow has a tendency to release when performing activities around the head."

5. "Unable to open TD at these positions."
6. "Do not have good control of arm in general, especially TD, harness will slip if arm attempts to reach mouth."
7. "When elbow flexed up 90°, loses control."
8. "Cannot open TD once positioned."

When asked if their present prosthesis snags clothing during operation 62 percent responded yes while 31 percent reported no problems. The following were some of their comments pertaining to this issue:

1. "Specifically at the cable and pivot points of the elbows"
2. "When getting dressed, and bunches in elbow limiting elbow flexion"
3. "Taking clothes on and off, arm will snag"
4. "Hooks on pants or jackets"
5. "It wears out clothes in certain areas"
6. "TD snags on loose fitting clothes"
7. "Sweaters snag on TD and cable housing."

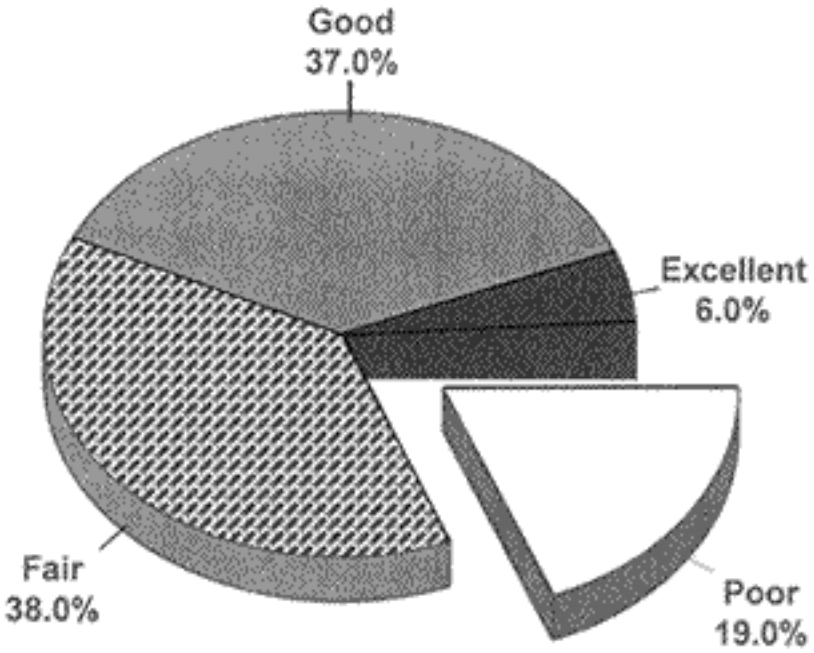

Figure 4. *Subject's overall rating of present prosthesis (N=16).*

Figure 4 shows subjects' overall rating of their present arm. Subjects who gave a *Poor* or *Fair* rating made the following comments:

1. "Poor design."
2. "Due to my severe level of amputation, it was difficult to get the arm to function for any type of activity."
3. "Limited range of use for TD function and excessive body motion required to operate."

4. "Not made for someone to do everyday things--never sure arm will work right when needed; Cables snap and have to ask others for help."
5. "Using same type of arm 50+ years and should be better comfort and function."
6. "Not totally pleased with functionality of prosthesis and looking for a more energy efficient responsive prosthesis."
7. "Elbow controls are poor."

Fitting/Training of the AdVAntage Arm

Sixteen fittings were completed during the clinical evaluation. Fourteen were unilateral and two were bilateral. Subjects were given the option of keeping their Arm for continued use at the conclusion of their clinical trial. Those Arms that were not kept were refitted to other subjects, which resulted in a larger number of fittings than Arms.

The Arm was distributed to the respective local prosthetists (identified by the field PI) to complete the fitting and associated training of the subjects. The prosthetists were asked to complete the fitting instrument for each subject. This instrument also included questions pertaining to the subjects' training. Out of an expected 16 instruments, 15 were completed and returned to TTS.

Compared with fitting conventional AE arms, 20 percent felt fitting the AdVAntage Arm was easier, 20 percent reported it to be the same, while 60 percent rated it more difficult to fit. A User's Manual was provided with shipment of each Arm. This manual gave information for fitting, training, and checkout of the Arm. The prosthetists provided the following collective recommendations for revision of the instructional manual:

1. Instructions did not clearly explain the smart function of the elbow. Diagrams/ schematics of elbow set-up need to be included. Guidelines are needed for cable routing and adjustments, and wrist installation, and requirements are needed for adjusting TD tension/slack cable for setting up the TD in both pronation and supination. Difficulty was experienced when deciding where to set knot for terminal ball. It would be worth noting the position of the tension take-up pulley.
2. The type of wrists to be used with arm should be included.
3. Having an instructional video available showing set-up and assembly of arm should be considered.
4. A troubleshooting guide should be included. An example of a problem would be how to attach the TD cable to the TD. The instructions did not explain that the cable had to be pulled as far as possible before attaching it to the TD. The fitting was more difficult due to minimal instructions.
5. Technical/functional specifications for the arm (i.e., lifting limit when elbow locked at 90°) should be provided. A discussion of variables between this elbow function and the Hosmer elbow should also be included.
6. Guidelines for cosmetic covering should be included. Problems were experienced with a soft cover fabricated over the forearm. This made adjusting the forearm lift

knob very difficult when changing TDs of different weight. A finishing kit is needed--"right now it is a guessing game."

7. The fact that the elbow does not fully extend (has 10°-15° flexion) needs to be addressed. It may be important to some users to have full extension at the elbow.
8. Training guidelines with diagrams to illustrate control motions of elbow operation (i.e., elbow lock/unlock movements) should be included. It is difficult for the user to know when the elbow lock has been actuated.
9. The three-lift assist springs available for use with the arm should be identified.
10. Unilateral versus bilateral fitting requirements need to be fully addressed.

During the initial fitting phase, the HOSMER Passive Wrist Unit # 71983 and the HOSMER Constant Friction Wrist Unit # 71988 were identified for use with the AdVAntage Arm.

Prior to shipment of the Arm for fitting, prosthetists were asked to identify whether their subjects used a quick-disconnect wrist unit and if a heavier lift assist spring would be required. A wrist interface adapter, custom-made by the manufacturer, was provided for use with the quick-disconnect wrist and the appropriate lift assist spring was installed before shipment of the arm to the prosthetist.

In all instances, subject training was required. Sixty percent of the prosthetists found the length of training time to be acceptable, while 40 percent felt that it was unacceptable. More than half of the subjects were long-time wearers of their arms and required a longer period to appropriately control the elbow and TD; specifically, the proper shoulder motions necessary for getting the control cable to lock/unlock the elbow and actuate the TD. Prosthetists also reported subjects experiencing some frustration in knowing when, and if, the elbow lock had been actuated. Overall, 13 percent of the prosthetists rated the training requirements excellent; 47 percent rated them satisfactory, and 40 percent rated them as poor.

Prosthetists were also asked to rate the features shown in **Table 4:** For any ratings of *Fair* or *Poor,* the following comments were provided:

1. "Due to unfamiliarity with product and quality of cable material."
2. "Limits possibility of quick disconnect for use with various terminal devices."
3. "Use of a soft cover made adjusting the forearm lift knob very difficult when changing to TDs of different weight."
4. "Shortening of cable housing is complicated because of polymer lining and type of cable used. There is too much friction at outlet to TD."
5. "Some difficulty was found when deciding where to set knot for terminal ball."
6. "Poor means of determining what cycle elbow controls are engaged."
7. "Difficult to thread the nylon through housing and cut housing to length and

rethread (time consuming)."

8. "Multiple shortening of the forearm and cable housings were very labor intensive and required specialized procedures to do them."
9. " In the E-400 elbow only one motion was required for a state change. In the AdVAntage elbow, at least two motions are required for the same state change. This means more overall motion for the patient."
10. "The TD cable, with its posterior exit point, has caused some difficulty when rotating the TD. The housing must wrap around the forearm tube when the TD is rotated to the extreme position and supination. Would prefer an anterior cable exit to TD for a more direct pull."

Table 4.

Prosthetist's rating of features of AdVAntage Arm (N=15).

FEATURES	% GOOD	% FAIR	% POOR
Front Elbow Hinge	53	40	7
Dual Cable Control	33	47	20
Spring-Powered Cable Recovery	67	26	7
Adjustable Cable Pull-Life Assist	60	27	13
Internal Cable Routing w/Polymer Material	13	54	33
Weight	93		7
Maximum Elbow Flexion Angle	93		7
Actuation Cable Excursion	80	7	13
Elbow Locking Positions	73	27	
Adjustable Forearm Length	73	20	7
Shoulder/Humeral Motions	53	20	27

Prosthetists were asked to compare the Arm with conventional body-powered arms in specific areas shown in **Table 5.**

For any rating of *Worse,* the following comments were given:

1. "The forces required to flex a conventional elbow-forearm system can be modified in two ways: the forearm lift assist and the location of the forearm lift tab. The latter has been very useful to modify these forces when using different TDs and varying forearm lengths. The AdVAntage Arm, not having a variable lift tab, must rely on the spring assist. I think it needs easier adjustment and greater potential for

assist."

2. "The subject experienced some frustration in knowing when the elbow lock has been actuated. I believe his conventional system has more resistance and also offers the two audible clicks as feedback."
3. "In using a shoulder saddle harness over a figure-eight, the route of the toggle cable is just inferior to the axilla. This has caused difficulty in activation for subject when wearing a coat. I think added resistance would help this."
4. "The elbow is larger even though the forearm is smaller. A custom cover has to be made."
5. "At full flexion, elbow lock/unlock does not always (consistently) function as it should. It takes several attempts at getting control cable to allow lock/unlock."
6. "Cable routing more complex."
7. "Tubular construction not realistic looking. Requires cosmetic cover."
8. "Elbow range of motion does not come into full extension."
9. "Not acceptable when an individual wants various TDs (i.e., golfing, fishing, and hand attachments)."
10. "When you remove cable from TD, elbow becomes non-functional, unlike conventional arm. The elbow cannot be locked into position for a fishing pole TD which does not require TD control."
11. "Location of housing--the way it exits the cosmetic cover is poor. It makes rotation of the wrist difficult."

Table 5.
Prosthetist's comparison of AdVAntage Arm to conventional body-powered arms (N=15).

FEATURES	% BETTER	% SAME	% WORSE
Weight	100		
Cosmesis	27	27	46
Elbow Range of Motion	60	27	13
Flexion Angle	53	40	7
Terminal Device Control	53	27	20
Elbow Lock Control	7	40	53
Cable Routing	20	20	60
Actuation Cable Excursion	40	47	13
Lift Assist/Gain	33	60	7
Elbow Locking Positions	27	73	
Adjustable Humeral Rotation Friction	7	93	

State Change Control	33	27	40
Function	43	37	20

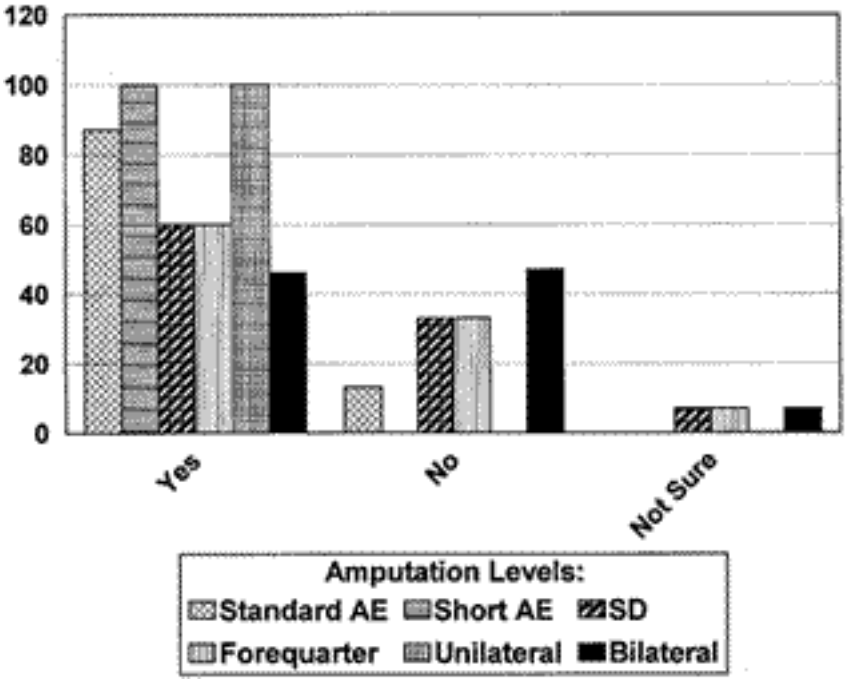

Figure 5. *Prosthetist's recommended amputation levels for prescription of the AdVAntage Arm (N=15).*

Figure 5 indicates various amputation levels that the prosthetists felt would benefit from using the Arm:

Prosthetists who indicated *No* for use of the Arm by the above amputation levels gave the following comments:

1. " Not for anyone who wants a hand or any specialty TD attachment."
2. " Because of the increase of shoulder motions required for the state change, would make it difficult for users with shoulder disarticulation (SD), forequarter, and bilateral amputations."
3. " Harnessing issues need to be resolved for bilateral consideration."

As indicated earlier, there were two bilateral fittings. Harnessing problems were experienced that inhibited one subject's ability to function with the Arms. He had a bilateral short THA. For a person with bilateral THA, each control cable is dependent on the opposite arm (i.e., to open the left TD, the right prosthesis provides the support). As this subject would try to open his left TD, the hanger and actuator cable on the right prosthesis would shift toward the left. This resulted in the subject not getting adequate excursion of cable/harness system through either bilateral scapula abduction or humeral flexion. As the subject tried to open the left TD, the right arm uncoiled causing the hanger to shift left. The rewinder on each arm must have a more positive stop to prevent

uncoiling of opposite arm. The subject was not able to get either TD to mouth (the TDs missed by approx. 20.32-22.86 cm).

The second subject with bilateral amputation had a short THA on the right and a forequarter on the left. His fitting was completed and he has been able to function with the arms.

Out of the 14 unilateral fittings, four involved short THAs, of which two were on left side and the remaining two on the right. There was a reported problem with fitting one of these subjects. The subject had a very short (2.54\7.62 cm) residual limb on the left side. The prosthetist felt that the elbow provided functioned as a right elbow. Even though he was able to complete the fitting, he indicated that the harnessing and suspension, in conjunction with the right and left side problem, were responsible for many of the fitting problems he encountered with this subject.

The above issue concerning right and left sidedness was brought to the attention of the manufacturer. In providing a response, they reviewed the matter with a consulting prosthetist. While both the control cable and lock/unlock cable are offset from midline toward what would be the subject's left, it does not necessarily compromise the ability to effectively fit a right THA. However, the prosthetist cannot use the same standard control cable routing and mounting for an individual with amputation on the right as he can with one on the left. In routing the cable in case of the former, one must use more of a European style cable routing in which the cable is routed more toward the medial side of the socket rather than the lateral side as is typical in the United States. While this may be somewhat unusual, it has little apparent effect on the efficiency of the control cable, since most of the fittings went well. Based upon this information, a section will be added to the instructional manual instructing prosthetists on how to route the cables to include the total fitting.

Five prosthetists were able to provide a custom cosmesis for the Arm using a soft forearm cover. Each accomplished this, based upon his or her prosthetic experience, since no instructions addressing this topic were included in the manual. There were difficulties encountered that included the inability to adjust lift assist after the cover was in place.

Subject Response (30- and 90-Day Post-AdVAntage Arm)

Subject trials consisted of a 30- and 90-day follow-up from the date of completed fitting. At the end of each follow-up period, the subject was asked to complete a data instrument to record responses pertaining to each subject's use of the Arm. This comparative data assessed the Arm for improved function and utility over the subject's conventional body-powered AE prostheses.

Subject Response (30-Day Post-AdVAntage Arm):

An overall synopsis of the subjects' responses with regard to performance and characteristics of the Arm was made from data received and a review of their comments.

A majority of the subjects (74 percent) used the Arm for more than 5 hours per day and between 3-7 days per week (54 percent). In **Table 6,** subjects compared prosthetic features of the Arm.

Table 6.
Subject's comparison of AdVAntage Arm features: 30-days post (N=15).

FEATURES	% WORSE	% NO CHANGE	% BETTER	% N/A
Elbow Control	54	13	34	
Terminal device control	13	27	34	
Cable control system	27	27	46	
Ease of use	40	20	40	
Reliability	33	47	20	
Forearm Lift	13	40	47	
Cosmesis	27	33	40	
Noise level	20	40	40	
Weight	7	33	60	
Training	36	28	36	
Durability	20	60	20	
Donning/Doffing	13	74	13	
Suspension system	7	80	13	
Comfort	13	27	60	

Fifty-three percent of the subjects experienced some malfunction with his or her prosthesis. The elbow unit was the item that needed the most frequent repair or adjustment. The majority of these subjects found the length of downtime to be acceptable.

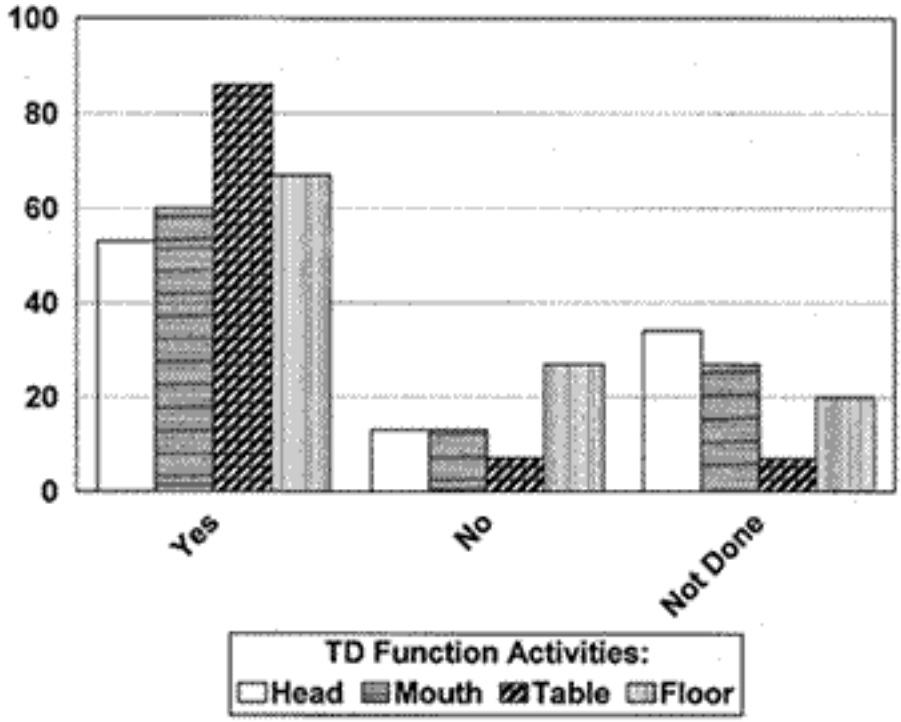

Figure 6. *Subject's rating of TD function of AdVAntage Arm: 30-days post (N=15).*

In **Figure 6,** subjects rated TD function of the Arm for specific activities. For any item rated *No* or *Not Done,* the following comments were provided:

1. One subject had limited use due to an unplanned hospitalization.
2. Not reliable enough when doing tasks.
3. Not able to use arm at and around head due to shoulder fusion (fused at 35° flexion and 15° abduction).
4. Needs more training.
5. Requires too much effort to operate.

Eighty-seven percent of the subjects indicated that the Arm did not snag their clothing during use. Forty-seven percent reported that using the arm has made it easier and allowed them to perform more activities of daily living. **Figure 7** provides subjects' overall rating of the AdVAntage Arm after completing 30-days use.

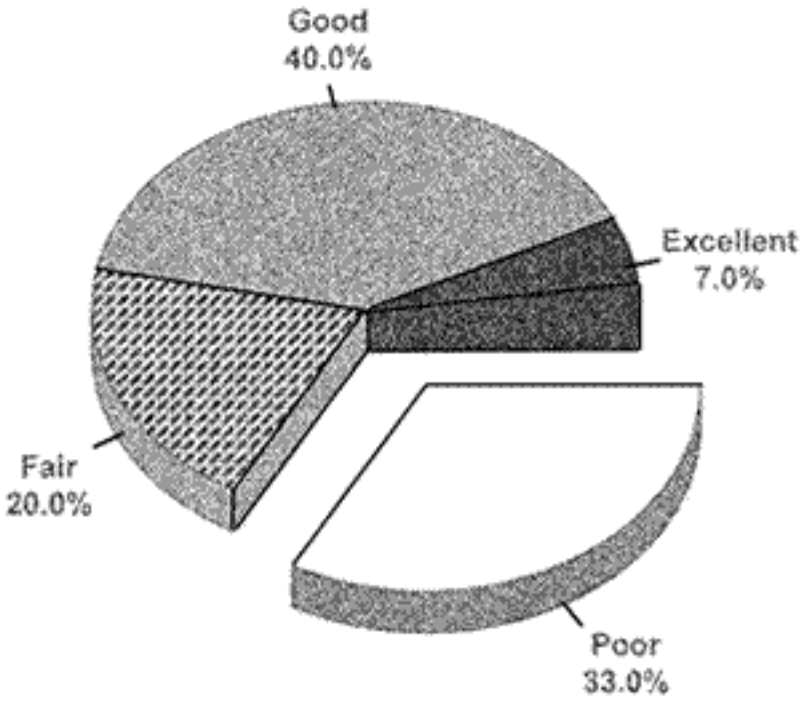

Figure 7. *Subject's overall rating of AdVAntage Arm: 30-days post (N=15).*

Subject Response (90 -Day Post-AdVAntage Arm):

After 90-days use, 11 subjects completed a 90-day data instrument. A majority of subjects (64 percent) continued to use the Arm for more than 5 hours per day and between 3-7 days per week (55 percent). In **Table 7,** subjects compared prosthetic features of the Arm to their present prosthesis. Seventy-three percent experienced some malfunction with their current prosthesis. The elbow unit most frequently needed repair or adjustment. The majority of these subjects found the length of downtime to be acceptable.

Table 7.
Subject's comparison of AdVAntage Arm features: 90-days post (N=11).

FEATURES	% WORSE	% NO CHANGE	% BETTER	% N/A
Elbow Control	46	18	36	
Terminal device control	9	18	73	
Cable control system	27	27	46	
Ease of use	36	18	46	
Reliability	36	28	36	
Forearm Lift	27	18	55	
Cosmesis	18	55	27	
Noise level	36	18	46	

Weight		36	64
Training	27	46	27
Durability	18	46	36
Donning/Doffing	9	82	9
Suspension system		73	27
Comfort		36	64

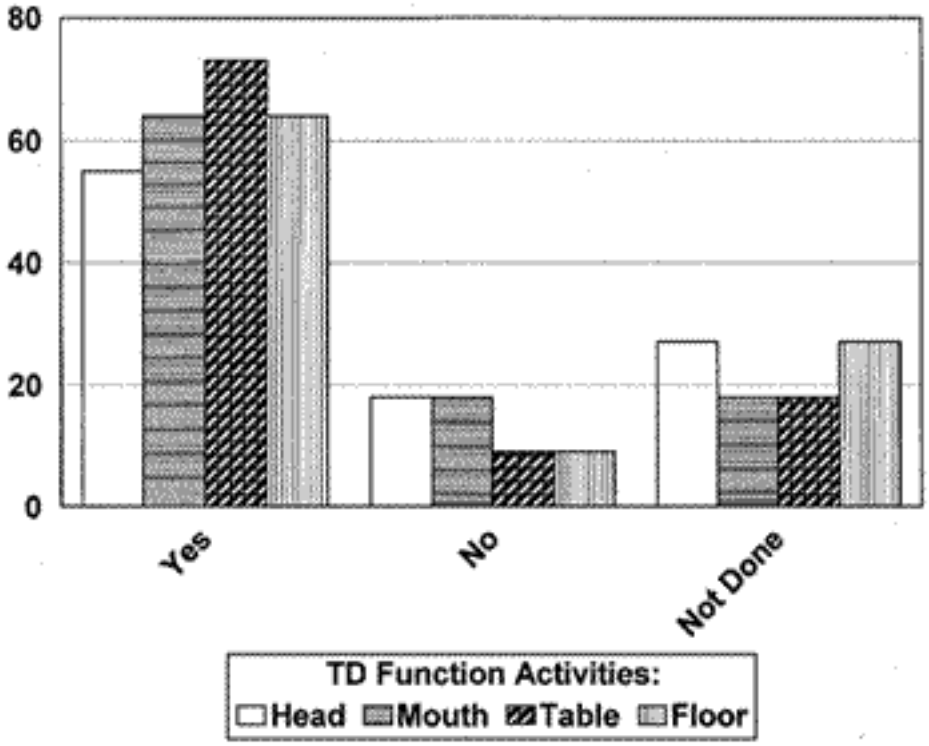

Figure 8. Subject's rating of TD function of AdVAntage Arm: 90-days post (N=11).

Figure 8 provides subject's rating of TD function using the Arm for specific activities. For any item rated *No* or *Not Done*, the following comments were made:

1. "Cannot reach side of head secondary to shoulder fusion."
2. "Can't tell when elbow is locked to open TD."
3. "More training needed."

Eighty-two percent of the subjects indicated that the Arm did not snag their clothing during use. Fifty-five percent reported that using the arm has made it easier and allowed them to perform more than ADLs (i.e., putting seeds in bird food hopper; Working in cramped positions such as under the sink, kneeling, or working in the garden; working on fine detail tasks such as puzzles and hobbies; holding and shooting a rifle).

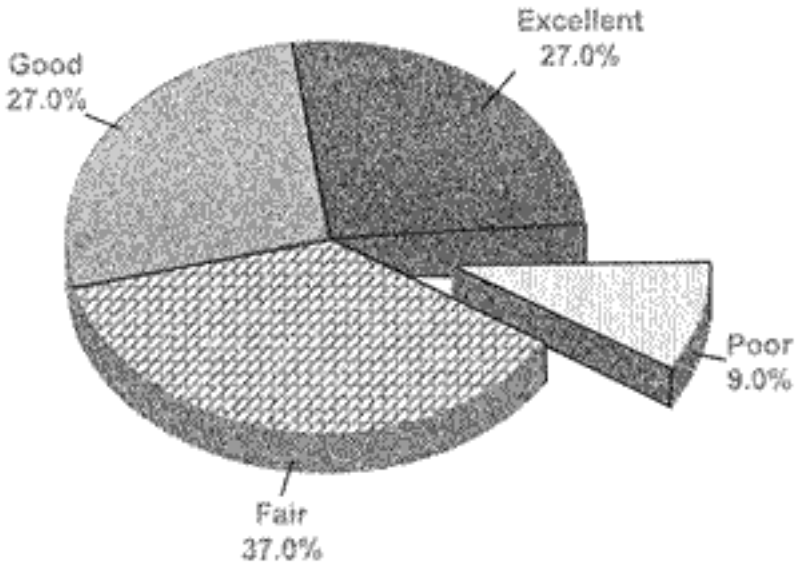

Figure 9. Subject's overall rating of AdVAntage Arm: 90-days post (N=11).

Figure 9 provides subjects' overall rating of the Arm after completing 90-days use, with the following general:

1. "The arm can be adjusted to fit my needs."
2. "It functions in a more fluid manner, requiring less energy."
3. "It is lighter."
4. "The cloth cable has a lower coefficient of friction than the conventional steel cable and housing. This reduces the energy I use to lift the forearm and open the hook."
5. "Better control of TD especially at outstretched or overhead positions."
6. "Once elbow is locked, the hook works at all angles."
7. "The arms are much more comfortable and enable me to do things with much more ease."

At the conclusion of their clinical trials, 10 subjects elected to keep the Arm for continued use. Nine of the subjects had unilateral amputation with seven having standard length THA levels and two with short THA. Two of these subjects had limited shoulder ROM. The one bilateral subject had a short THA on the left side and a forequarter level on the right.

Of the six who did not keep the Arm, five were unilateral and one was bilateral. Of the five unilateral subjects, three had standard length THA, and two had short THA. One subject suffered a mild stroke and had to return the Arm. The subject with bilateral amputation had short THA levels on both sides. Several of the subjects remarked that if the suggested modifications were incorporated into the Arm, they would be willing to try it again.

Maintenance and Repair

During the course of the clinical trials, instances of product failure were reported and documented on the evaluation maintenance and repair log (TTS 105 data instrument). The manufacturer provided technical assistance to all participating sites throughout the trials and assigned a technical liaison to handle all problems identified by the field. All technical issues and malfunctions were handled in an expeditious manner, which ensured continuity of the clinical trials. The following is a summary of the problems and resolutions: [nl]1. Three failures occurred that involved the elbow locking pin sticking. The arms were shipped back to the manufacturer for pin adjustment. Based upon this problem, the pin adjustment was made to all subsequent arms.

- Five failures were reported that involved breakage of the forearm housing collar. Based upon this failure, the manufacturer recalled all arms that were in the field and retrofit each with a re-engineered part, which should better withstand the rigors of everyday use. All subsequent arms were then fit with this upgraded part.
- Five arms were fit with a heavier lift-assist spring based upon the user's need.
- TD control cable and housing broke and required replacement.
- One instance of TD cable fraying was reported which led to the recommended use of a ball cable adapter [9/32" Ball (HOSMER) # ASPCB2 ball cable adapter] for all arms.
- Several of the cogs in the sprocket were damaged when a subject was doing push-ups. The arm was shipped to the manufacturer who made repairs and returned the arm.
- For all arms that used a quick-disconnect wrist, the manufacturer custom-made a wrist interface.
- There were several instances of inconsistent elbow lock/unlock operation. In each instance, the elbow was shipped back to the manufacturer for checkout and adjustment. It was difficult to discern if the problem was isolated to the elbow or involved the harnessing arrangement. This particular issue has been discussed between the manufacturer and the respective prosthetists and will require further scrutiny on the part of the former.

DISCUSSION

Results from the clinical trials demonstrated that the Arm (with revised design changes) could be fit for use by individuals with THA. Once the subject developed expertise and overcame the learning curve, the Arm offered several functional advantages over conventional arms. Its overall lightweight, unique separation of the elbow movement mechanism from TD actuation, and cable recovery system, which allows opening and closure of the TD at any elbow position using the same cable excursion, proved beneficial for many of the THAs.

Resultant data led to the following summation of the precommercial AdVAntage Arm:

Advantages

- Lightweight
- Cable excursion in full flexion
- Increased function of TD with less effort especially in close proximity to the body, in outstretched and overhead positions, and at all flexion angles in and around the head and face area
- Adjustability
- Increased activities from waistline and above
- Use of Spectra® cabling reduced friction and energy required lifting forearm and opening TD.

Disadvantages

- Inconsistent elbow lock/unlock mechanism
- Learning curve (extra shoulder movements to operate elbow)
- Inadequate instructional materials for fitting and training
- Poor means of determining what cycle elbow controls are engaged
- Lack of a cosmesis
- Noise level associated with ratchet proved disturbing
- Does not permit for the changing of TD for vocational and avocational function.

Prescriptive Indications

The AdVAntage Arm, in its present configuration, would be indicated for use by persons with unilateral THA with

- Standard TH amputation level
- Shoulder limitations (i.e., shoulder fusion)
- Short THA level (dependent upon harnessing arrangement).

The Arm would be indicated for use by persons with bilateral THA dependent upon the harnessing arrangement, which must be able to provide proper separation of control.

Contraindications

The Arm, in its present configuration, would *not* be indicated for persons

- Who are long-time users with low tolerance for relearning shoulder movements for operating elbow
- With poor hearing (not able to determine what cycle elbow controls are engaged)
- Who utilize a hand or specialty TD attachment.

Recommended Modifications

Primary

- Improve consistency of elbow locking/unlocking mechanism
- Need to accommodate varying harnessing arrangements used by persons with bilateral and short THA
- Improve durability of forearm tube and elbow attachment for heavy-duty users
- Improve instructional and training materials (should include notice about elbow flexion around head and face)
- Provide a cosmetic cover that is durable and washable.

Secondary

- Decrease the number of steps to operate the Arm
- Make the rewind mechanism stronger to avoid unwinding of cable for bilateral use
- Dampen noise from the ratchet
- Improve sensory feedback for elbow locking
- Allow for use of specialty TD attachments and hand.

CONCLUSION

Based upon the results of this multi-center clinical evaluation, the Arm offers improved function over existing body-powered arms and can be prescribed for use by appropriate persons with unilateral and bilateral THA.

The modifications identified during the clinical trials have been brought to the attention of the manufacturer, who has provided the following solutions to most of the identified issues. Several may require more investigation and further consumer feedback from the commercial market.

1. Prototype cosmesis designed and fabricated
2. New manual completed, including revised fitting instructions and training section
3. Lock pin redesigned to improve consistency of lock/unlock position
4. Improved isolation to decrease ratchet noise
5. QD wrist adapter for TD replacement (Hosmer components)
6. Forearm, humeral pieces and lock pin redesigned for increased strength and durability for heavy duty use

The ability of the manufacturer, who is committed to the commercial marketing and

technical support of the Arm, to handle technical issues as they arose was demonstrated throughout the clinical trial by their quick resolution and turnaround time. The modifications, as identified in this report, are provided to guide the manufacturer and will only serve to enhance the Arm's performance, clinical application, and commercial success.

As a result of the VA's partnership in the technology transfer of this product, there will be preferential pricing for all federal purchases of the Arm. In addition, all commercial literature will credit the Department of Veterans Affairs Rehabilitation Research and Development Service for sponsoring the research, development, and technology transfer of this product.

RECOMMENDATION

Results of this clinical evaluation demonstrated that the AdVAntage Arm has proven to be acceptable for use by appropriate veterans with amputation. The AdVAntage Arm is recommended for commercial production.

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