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CLINICAL REPORT

Clinical Evaluation of the Modular Electromechanical Lock Actuator (MELA) for Above-Elbow Prostheses: A Final Report

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Abstract—The Modular Electromechanical Lock Actuator (MELA) is the result of research and development (R&D) conducted under the direction of Dudley S. Childress, PhD, at the Northwestern University Prosthetics Research Laboratory (NUPRL), Chicago, Illinois. NUPRL, based upon experience with prostheses for persons with high-level, above-elbow amputations, developed the MELA to assist those persons with amputation who experience difficulty in operating existing manual elbows, whether with a conventional harness, nudge control, excursion amplifier, or other arrangement.

Technology Transfer Section, VA Rehab R&D, with collaboration from Frederick Downs, Jr., Director, and John Clements, Prosthetic Regional Manager, VA National Prosthetic and Sensory Aids Service, managed a multicenter clinical evaluation of the MELA. The purpose was to objectively assess and affirm its performance, safety, clinical application, and commercial readiness.

The following VA Prosthetic Treatment Centers served as evaluation sites: Baltimore, MD, Huntington, WV, and New York, NY. A VA-wide screening process yielded 10 candidates for review. A total of seven subjects met the selection criteria and were accepted for participation. In addition, several prosthetists provided their comments on the MELA. Overall, the performance of the MELA demonstrated that it could be fit to existing body-powered arms and used as an alternative control method for manual elbows. Consensus of participant feedback indicated general satisfaction and improved elbow lock function. In addition, several modifications were identified for the commercial version. The primary issues focused on 1) increasing speed (alternating response time); 2) unloading forearm (sometimes required to cycle the MELA); 3) providing mechanical back-up in case of unit failure; 4) reducing gear-motor noise; 5) improving integrity of wiring and retaining clip; and 6) marketing the MELA as a stand-alone product.

Hosmer-Dorrance Corp., in collaboration with the developer, has indicated that resolution for most of the identified issues is readily achievable. Increasing speed (response time) and unloading forearm will require more investigation and consumer feedback from the commercial market. Based upon the clinical findings, the MELA was recommended for commercial production and availability, upon prescription, to appropriate veteran beneficiaries.

Key words: *clinical evaluation, high-level above-elbow amputation, manual elbows, MELA, modular electromechanical lock actuator, technology transfer.*

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INTRODUCTION

One of the highest priority areas of the Department of Veterans Affairs, Rehabilitation R&D Service (VA Rehab R&D), involves prosthetics, amputations, and

orthotics. The VA supports development in this area, which results in artificial limbs that are lighter, better fitting, more comfortable, and permit the user more natural movement for activities of daily living (ADL) and more rigorous activities, such as running, skiing, and so forth.

The VA Rehab R&D Service supported the development of a modular electromechanical lock actuator (MELA) for above-elbow (AE) prostheses (**Figure 1**). This development effort was conducted under the direction of Dudley S. Childress, PhD, at the Northwestern University Prosthetics Research Laboratory (NUPRL), Chicago, Illinois.

When the R&D Principal Investigator completed the development phase, the MELA underwent a multicenter clinical evaluation. A collaborative effort was managed by the VA Rehab R&D Technology Transfer Section (TTS) and involved the developer (NUPRL), the manufacturer (Hosmer-Dorrance Corp.), and the VA Prosthetic and Sensory Aids Service (PSAS) of VA Headquarters (VAHQ).

The purpose of the multicenter clinical evaluation was to determine the acceptance of the the MELA by the target population and to identify any modifications that may be needed to improve optimal use of the product and to enhance its marketability. The following specific areas were assessed:

- Prescription indications and contraindications
- Fitting (i.e., compatibility with existing body-powered prostheses)
- AE componentry (use of existing versus special techniques, knowledge, tools, and so forth)
- Training requirements
- Instructional materials (i.e., supplied manuals and/or tapes will be evaluated for clarity, effectiveness, and completeness)
- Functional use and activities
- Comparative acceptance to other alternative arrangement for existing, body-powered elbow lock control
- User acceptability in terms of ease of operation, cosmesis, and functional advantages
- Reliability
- Durability
- Maintenance and repair
- Readiness for commercial availability.

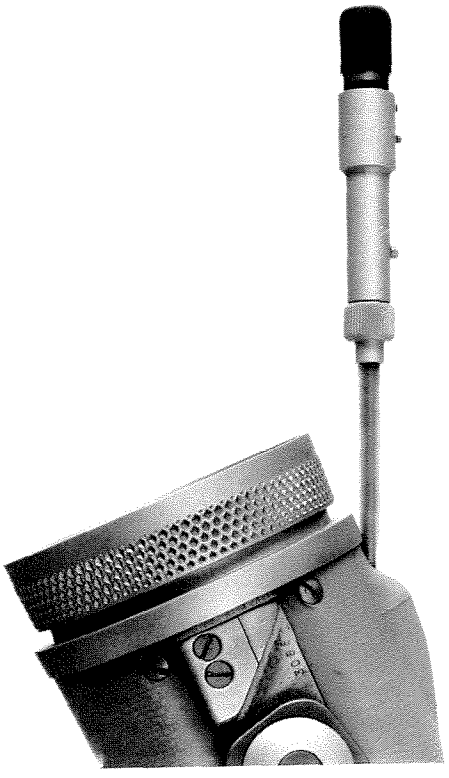

Figure 1.
Modular Electromechanical Lock Actuator (MELA).

Description

A description of the physical appearance of the MELA is given in the preliminary report (1).

The MELA is a simple, modular, electrically powered lock actuator used in conjunction with existing cable-operated, positive-locking elbow and wrist components. A momentary switch contact is all that is necessary to operate the system through the electronic circuit. When the motor is activated, the nut retracts; thus, pulling the cable and unlocking the mechanism. The next activation extends the nut; thereby releasing tension in the cable and allowing the spring loaded mechanism to lock. Each activation alternates between locking and unlocking. The MELA can be installed inside or outside the prosthesis (**Figure 2**), depending upon whether the elbow has either an inside or outside cable exit and space available inside the socket (2).

A claimed principal advantage of the MELA is the lowered force required to operate an electrical switch versus the physical movements presently necessary for mechanical elbow lock control of a body-powered AE prosthesis. Greater options for placement and configuration of the switch control over that which is possible with existing cable or lever controls was viewed as its second advantage.

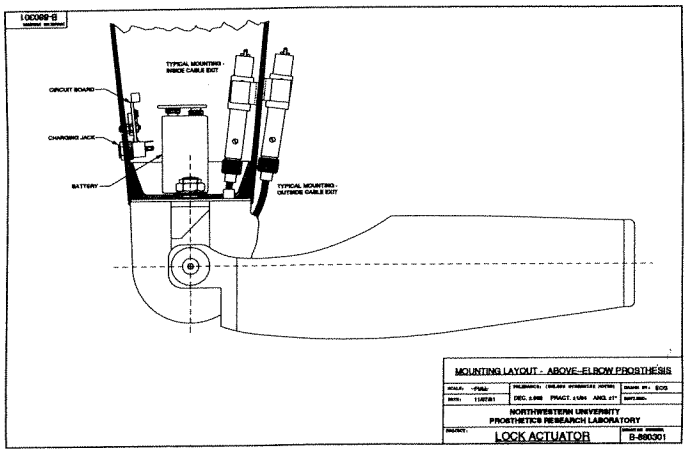

Figure 2.
Typical mounting arrangements on Hosmer-Dorrance E-400 elbow with either outside or inside cable exit.

BACKGROUND

The developers at NUPRL believed that body-powered, positive-locking components, with their comparative mechanical simplicity, general ruggedness, and low cost, had not been fully exploited. They felt that the mechanical AE prosthesis offered a significant advantage by providing a close coupling between the user and the prosthesis, since the cable control uses the person's otherwise intact musculoskeletal and sensory systems for elbow/prehensor control and to position positive-locking wrist components (for rotation and flexion). The dependency on mechanical linkages to operate the locking mechanisms in these prostheses limited their effectiveness for the user and complicated the prosthetic fitting. This concept led to the design of the MELA.

The developer felt that practitioners would prescribe the MELA because of its potential to augment existing body-powered prostheses; consequently, providing improved functional expectations and increased independence for persons with high-level AE amputations.

FUNCTION

The electromechanical lock actuator and the electronic circuit are powered by a single 9-volt rechargeable battery. The device consists of a 10 mm diameter gear-motor driving a steel screw into a brass nut. A steel cable is attached between the nut and the mechanical locking mechanism. The MELA weighs only 0.92 oz (26 gms) and does not contribute significantly to the total weight of the prosthesis. Its overall length is 3 inches (76.2 mm).

CLINICAL EVALUATION METHODS

Evaluation Models

TTS procured 12 precommercial models of the MELA for evaluation purposes. These models were manufactured by the Hosmer-Dorrance Corporation (Campbell, CA), which is committed to manufacturing and delivering the MELA to the commercial market.

Site Selection

Prosthetic Treatment Centers (PTC) at the following VA Medical Centers (VAMCs): Baltimore, MD; New York, NY; and Huntington, WV, participated in the clinical evaluation trials. A field participating investigator was designated to coordinate evaluation activities at each site.

Subject Selection

With collaboration from the Director, PSAS, VAHQ, TTS coordinated the subject selection for the MELA clinical evaluation. The MELA can be used with any type of prosthetic socket. The following criteria, provided by the developer, were used for screening appropriate subjects for the MELA:

1. The subject must be a body-powered AE or higher prosthetic user who has difficulty operating existing mechanical elbow lock, whether with a conventional harness, nudge control, excursion amplifier, or other alternative arrangement to assist in elbow lock control.
2. The study must include unilateral and bilateral fittings.

Two methods were employed to solicit veteran subjects. The first used the PSAS/VAHQ Hotline to announce the evaluation and subject criteria. (The Hotline is transmitted to the local Chiefs of PTCs, VA-wide.) The second was an advertisement soliciting veteran volunteers, which was placed in the Disabled American Veterans' publication (March/April 1994).

Potential subjects completed data instruments assessing their current physical and prosthetic function.

This information was reviewed for approval by the PSAS/VAHQ, NUPRL, and TTS to ensure that each intended subject fully met the stated criteria.

Each approved subject received information on the purpose and significance of his participation in this evaluation. Informed consent was obtained from each subject prior to fitting, in accordance with the requirements of the Institutional Review Board of each VAMC. A total of seven subjects participated in the clinical evaluation.

Fitting Process

The fitting process was defined by the developer and manufacturer and described in the instruction manuals. These manuals were disseminated to each field participating investigator. TTS covered the cost of the MELA, new elbow assembly and switch, fitting, and overnight shipment. The manufacturer modified elbow turn tables, as needed, at no charge. The developer stated that there were no special fitting methods required. The MELA does not have to be modified to fit a particular situation.

Due to the small number of subjects participating in this evaluation, it was felt by both the developer and manufacturer that the results could be greatly influenced by the skill of the prosthetists who installed the MELA. In order to ensure uniform installation of the MELA, (and allow evaluation of the MELA itself), it was requested, by the developer and manufacturer, that the MELA be fitted to a new elbow by the manufacturer.

The new elbow, with the MELA installed, was fitted to each subject's prosthesis (**Figure 3**). The local prosthetist was required to mark, on the humeral section of the subject's prosthesis, the location for the following: push switch (NY single function, P/N 53036), battery, battery charger receptacle, and PC board. If the switch of choice was different from the push switch, the prosthetist specified the desired switch and location. The instruction manuals indicated that any of the single function momentary contact switches, commercially available for prosthetic applications, could be used for this application.

The manufacturer, upon receipt of the arm, fit a modified E400 Hosmer elbow, with the MELA, and then shipped all assembled components, together with the old elbow and parts, back to the specified local prosthetist for final check-out, delivery, and subject training.

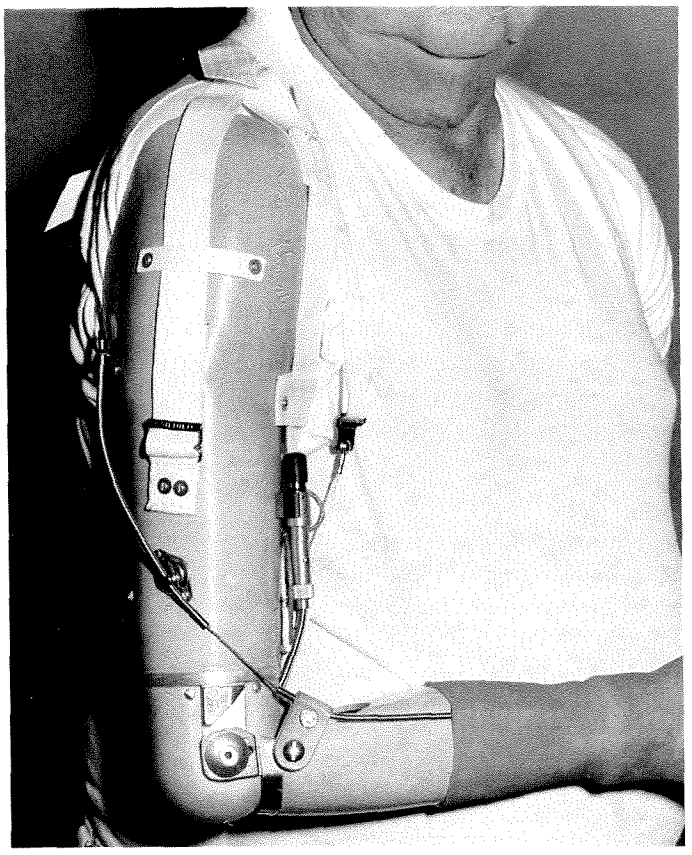

Figure 3.
The MELA externally mounted on subject's prosthesis with harness switch.

Training Requirements

As stated in the instruction manuals, the training requirements for operating the MELA were comparable to those for any switch-activated prosthetic component. It noted that the user should be informed that the actuator cycles from locked to unlocked to locked each time the switch is operated. The user should also be advised that in order to unlock the elbow, it is necessary to apply tension to the elbow control cable after the MELA has been operated to "unload" the lock mechanism and allow the locking bar to move to the unlocked position.

Maintenance and Repair

The instruction manuals provided a section for the prosthetist to follow that covered maintenance and repair procedures (i.e., lubrication, recharging, and several checks to perform in the event of system failure). It noted that periodic maintenance and repair was not usually necessary for the MELA; but to ensure

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optimum performance, the following should be observed:

- The MELA and its electronic control must not be exposed to excessive heat
- The MELA and its electronic control must not have direct contact with water
- Only the supplied battery charger is to be used.

As part of the evaluation protocol, the field participating investigator was provided with a log and instructed to record any instances when maintenance and repair were performed. The log was then to be submitted to the Project Manager, TTS.

Documentation and Data Management

Data instruments used for this evaluation were completed by the field participating investigator via interview with evaluation participants (i.e., subject and prosthetist). In addition, field participating investigators were requested to complete a data instrument regarding their experience with the MELA. Subjects completed pre- and post-response instruments assessing various aspects of the prosthesis. Data analyses for statistical measures and responses were tabulated using the Statistical Package for the Social Sciences (SPSS/PC+).

RESULTS

Seven subjects met the selection criteria and were accepted into the study. All subjects completed pre-fitting data instruments as well as 30-day postfitting instruments. Only five subjects completed a 90-day postfitting instrument. Two subjects did not respond for the following reasons: one subject voluntarily withdrew, citing the noisiness of the MELA as unacceptable for his use; the second subject required a lengthy fitting due to his choice of touch pad switch. It was discussed and decided that due to this subject's high activity level and to expedite the evaluation, he would not be required to complete this instrument.

TTS analyzed data for pre- and post-subject usage, fitting, and field participating investigator response instruments.

Demographic Characteristics

The demographic characteristics are based on the seven completed Subject Background and Subject Response (Pre-MELA) data instruments as shown in **Tables 1–3**. (One of the approved subjects was a bilateral AE amputee who received one MELA for fitting but chose not to be fit for a second MELA.)

Although the subject pool (**Table 1**) was limited in number, it was, however, indicative of the relatively small number of veterans with upper extremity amputations that utilize an artificial arm. PSAS, VAHQ reported that only 340 artificial arms were provided to this group of veterans during 1994 and that repairs were made to approximately 1600 arms during this time frame. This figure did not distinguish between persons with above- or below-elbow amputation or between manual and electric arms. "Statistics within the general population place the number of arm amputation in the US at 90,000 with about 50% choosing to wear prostheses. Of the 50% wearers of arm prostheses, levels of amputation are estimated as follows: shoulder – 5% and A/E – 23%"(3).

It is also interesting that the age distribution of the participating subjects was indicative of the aging trend within the veteran population. "It is estimated that the number of veterans 65 years and over is expected to increase from 8.3 million (1993) to a peak of 9.3 million in the year 2000" (4). In addition, these subjects were an active and experienced group of body-powered prosthesis wearers in an age range of from 18 to 50 years, and, as seen in **Table 2,** reflected a broad representation of various AE levels.

Two subjects reported using an excursion amplifier, one an external and the other an internal movable

Table 1.
Subject sample.

	N=7	%
Age Groups	31-45	14
	46-60	57
	61-75	29
Sex	Male	100
Presently Employed	Yes	71
	No	29
Type of Employment	Administrative	43
	Technical	14
	Other	14
	N/A	29
Amputation Type	Unilateral	86
	Bilateral	14
Years Since Amputation	<1	—
	1-5	—
	5-10	—
	>10	100

Table 2.
Above-elbow levels.

Amputation Level	Total Number
Forequarter	1
Shoulder Disarticulation (SD)	1
Short AE (50% or less of residual limb)	4
Long AE (+50%)	1

pulley. The subject using the external pulley has a shoulder disarticulation amputation level and the subject using the internal pulley has a short AE amputation level. **Table 3** provides a breakdown of the lock assists used.

Subject Response (Pre-MELA)

Prior to receiving the MELA, each subject completed a Subject Response (PRE) data instrument. This instrument gathered information on the subject's current prosthesis, which was used as comparative data for the precommercial product. It was found that all seven subjects used their prosthesis more than 5 hours per day each, and from 5 to 7 days per week.

On average, subjects indicated that it took 3–5 hours of training to feel comfortable using their prosthesis. One subject reported that he learned to operate his arm without the benefit of any training. **Table 4** presents the seven subjects' rating of their current prosthesis.

Prior to receiving a MELA, all but one subject reported difficulty operating their present mechanical elbow lock. This subject indicated that although operation of his elbow lock was satisfactory, he was looking for improvements.

The following comments reflect some of the disadvantages reported by the subjects concerning their (Pre-MELA) elbow locks:

1. "Must use remaining hand to operate lock cable."
2. "Cannot operate lock when lifting, sitting."
3. "When holding something, need to maneuver to lock and unlock—very inconvenient and awkward."
4. "When I lift something heavy, it locks and unlocks itself."
5. "Requires excessive motion and in certain body positions is difficult to engage."
6. "Lock mechanism undependable and fails frequently."

Table 3.
Use of elbow lock assists (N=7).

Assists Used	%
Waist band	14
Shoulder flexion on intact side	14
Other (use of sound hand)	14
N/A	58

Table 4.
Rating of prosthetic features: Pre-MELA (N=7).

	Percentages			
Features	Good	Satisfactory	Poor	N/A
Elbow Control	14	29	57	
Terminal Device Control	14	58	14	14
Elbow Lock Control		14	86	
Ease of Use	14	57	29	
Reliability	14	43	43	
Appearance	14	58	14	14
Battery Charging Procedure				100
Cable Control	43		57	
Noise Level	14	43	29	14
Weight		86		14
Safety		86	14	
Comfort	14	57	29	
Training	29			7
Durability	29	57	14	

It is well understood that unilateral amputees rely on their prosthetic arm for assistance during upper limb ADLs. The sound arm and hand becomes the dominant limb for all activities performed. Fourteen percent of the seven subjects rated their current prosthesis as *Good;* 57 percent rated theirs as *Satisfactory;* and 29 percent rated their current prosthesis as *Poor.*

Fitting and Training of the MELA

The MELA was distributed to the respective local prosthetists, identified by the field participating investigator, to complete the fitting of, and associated training for, the approved subjects. A total of seven fittings were completed for this evaluation project. Each prosthetist was requested to submit a completed data instrument (TTS-102) listing comments pertaining to both the fitting of, and training for, use of the MELA. Results are shown in **Tables 5–7.**

Fitting instructions were reported to be adequate; the time required to complete fitting was less than one hour. The fitting process was reported to be routine and subject training took less than one hour. The length of

Table 5.
MELA as compared with other prosthetic modifications (N=6).

Modifications	Percentages Better	Same	Worse	N/A
Nudge Control	50	33	17	
Chest Strap	50	33	17	
Waist Strap	33	50	17	
Perineal Control	67	17	16	
Excursion Amplifier		17	50	33
Addition of Axilla Loop	50	16	17	17
Addition of Shoulder Sling with Axilla Loop	50	16	17	17

Table 6.
Rating of specific features of MELA (N=6).

MELA Features	Percentages Good	Fair	Poor
Alternating response time between locking/unlocking the elbow	17	50	33
Force required to engage/ disengage the lock	67	17	16
Weight	67	17	16
Placement and configuration on switch control	17	50	33
Compatibility with existing body-powered prosthesis	33	50	17

Table 7.
Indicators for prescription of MELA (N=6).

Amputation Levels	% Yes	% No
Forequarter	50	50
Shoulder disarticulation	50	50
Short above-elbow	83	17
Unilateral	83	17
Bilateral	17	83

training time was rated acceptable and the general impression of the training requirements satisfactory.

Six subjects used the Hosmer-Dorrance E-400 elbow, while the remaining subject had an E-200 elbow. The E-400 elbow required only one modification when coupled to the MELA.

Two causes of a longer turnaround time than anticipated for the manufacturer to complete installation of the MELA were: 1) the prosthesis has an internal cable for locking/unlocking the elbow and 2) locating a membrane switch inside the humeral section of the socket, to allow the amputee activation by use of his residual limb.

Table 6 reflects the prosthetist's rating of specific features and operation of the MELA.

Prosthetists who rated certain features *Poor* indicated that "there was not enough power in the MELA to activate the elbow lock reliably." It was also noted that if this could be remedied that it would improve the function of the MELA.

Choice and location of the switch control were considered important elements for using the MELA. As noted in the instruction manual for prosthetists, the control switch of choice was the NY Single Function (push switch). It was also stated in the manual that any of the single function momentary contact switches, commercially available for prosthetic applications, could also be used.

One subject preferred the NY Single Function (push switch); one preferred the Liberty Touch Pad; and five preferred the harness switch. Each of the seven subjects used his switch of choice for this evaluation.

The subject who requested a touch pad (membrane) switch had the mounting accomplished inside the humeral section of his socket. This subject originally used a harness switch but found it unacceptable for his purposes. The subject who used the push switch had it originally located on the anterior humeral section of the prosthesis; this required the subject to use his sound arm to activate the switch. After usage, the subject felt the switch would be more functional if placed on the forearm, approximately 2.5 in (6.35 cm) proximal to the wrist unit and along the anterior lateral quadrant. This relocation provided the subject with greater ease of access by allowing him to use either his sound side or laterally moving prosthesis against an object (such as furniture) for switch activation.

Prosthetists indicated that the MELA would be suitable for use by persons with the amputation levels shown in **Table 7.**

Half the respondents indicated that, in its present design, the MELA may not be able to provide the necessary assist required for use by persons with high-level (30 percent or less humerus) amputation. If changes could be incorporated that focused on increasing power to flex and lock the elbow more easily, it may prove to be useful for the person with higher level amputation. In addition, it was noted that, due to the lack of mechanical override and slow response time, the MELA (in its present design) would be of little or no advantage to persons with bilateral amputations.

Subject Response (30-day Post-MELA)

An overall synopsis of the subject's response with regard to performance and characteristics of the MELA was made from the data received and a review of their comments. **Tables 8** and **9** reflect subject evaluation of the MELA after 30-day usage.

For items rated *Poor*, the subjects had the following comments:

1. "I could hear the motor working but the MELA would not disengage."
2. "When I was sitting down to type on my computer, the MELA would not release to go to another position."
3. "The MELA is very noisy."
4. "There should be a mechanical release in case the MELA should fail."
5. "There was hesitation when I would cycle the lock."
6. "Lack of feedback from the cable to provide perception of lock function."
7. "I had difficulty unlocking the elbow when there was a load on the forearm."

One subject commented that due to his extremely high-level of amputation (SD), that he realizes he is limited in what he can do. However, he felt the MELA had significantly improved locking/unlocking of his elbow.

The overall prosthetic rating (30-days post-MELA) of the seven subjects was as follows: 43 percent gave it a rating of *Good,* 43 percent rated it as *Satisfactory,* and 14 percent rated it *Poor.* The one subject who gave the rating as poor, reported that he "had to be very careful not to trip the switch and would want some way to turn the system off when not needed."

Subject Response (90-Day Post-MELA)

After 90 days' use, 5 subjects completed and submitted another questionnaire. **Tables 10** and **11** reflect their responses.

Table 8.
Prosthetic use (N=7).

Hours per day	%
1-3	29
5+	71
Days per week	**%**
<1	14
5-7	86

Table 9.
Rating of prosthetic features: 30-Day Post-MELA (N=7).

Prosthetic Feature	Percentage Good	Satisfactory	Poor	N/A
elbow control	72	14	14	
terminal device control	57	29		14
elbow lock control	57	14	29	
ease of use	57	43		
reliability	43	43	14	
appearance	43	43	14	
battery charging procedure	43	43		14
cable control	43	43		14
noise level	43	14	43	
weight	57	43		
safety	29	43	14	14
comfort	71	29		
training	57	43		
durability	29	57	14	

Table 10.
Prosthetic use (N=5).

Hours per day	%
1-3	0
5+	100
Days per week	**%**
<1	0
5-7	100

Table 11.
Rating of prosthetic features: 90-Day Post-MELA (N=5).

Prosthetic Feature	Percentage Good	Satisfactory	Poor	N/A
elbow control	60	40		
terminal device control	80			20
elbow lock control	40	40	20	
ease of use	60	20	20	
reliability	40	60		
appearance	60	40		
battery charging procedure	60	20	20	
cable control	60	40		
noise level	40	20	40	
weight	80	20		
safety	60	20	20	1
comfort	80	20		
training	80	20		
durability	60	40		

For items rated poor, the subjects had generally the same comments that were reported after 30 days of use. One subject indicated that he had a lot of difficulty when he tried to change the battery. Using his one sound arm, he was unable to manipulate the prosthesis to get the battery out or in. Also, while attempting this, the subject inadvertently tore the wires from the battery cable attachment to the charging section. He had to contact the prosthetist for assistance. The prosthetist made the repairs, but reported that he too had difficulty installing the new battery after the repairs were accomplished. Another subject reported the lack of feedback from the MELA elbow lock, as compared to body-powered elbow locks.

Sixty percent of the five users gave the MELA an *overall* rating of good, 40 percent rated it satisfactory, and none rated it as poor.

At the completion of their clinical trials, each subject was given the option of keeping the MELA. Two of the five remaining subjects elected to continue using the MELA.

Maintenance and Repair

During the course of the clinical trials, several instances of product failure were documented on the maintenance and repair log and submitted to TTS. Of the total of seven reported failures, four were resolved with on-site repair (using instruction manual or telephone), while the remaining three required off-site repair performed by the manufacturer.

In addition to these failures, there were three reports of the retaining clip (which holds the MELA in place) breaking off. In all instances, the prosthetist used either a Dacron strap or tape, which allowed the subject to continue using the unit.

DISCUSSION

Results from the clinical trials demonstrated that the MELA could be fit to existing body-powered arms and used as an alternative for operating the elbow locking mechanism. It was shown that the MELA could replace the high forces currently required to operate these mechanical controls, with the considerably lowered forces needed to operate an electrical switch controlling a motorized actuator. The MELA is intended to target those persons with high-level AE amputation who are having difficulty operating an existing mechanical elbow lock; whether with a conventional harness, nudge control, excursion amplifier, or other alternative arrangement to assist in elbow lock control. It is this group that experiences the most difficulty with body-control motions which can deter, or often discontinue, use of the body-powered prosthesis. Two of the seven selected subjects have requested to continue using the MELA.

"Of those arm amputees who wear prostheses, estimates suggest that usage of externally powered prostheses is at about 10%, having risen from about 5% in the last several years (5). In other words, 90% of amputees who use prostheses still use the body-powered type" (6). Factors such as "generally better function due to some sensory proprioceptive feedback from the harness, lightweight, better reliability and less breakdown, and simple "hassle-free" maintenance for the user" (7) continue to keep the body-powered device the arm of choice. This, despite the fact that "the overall weight is less, but to actually move the elbow, large forces are required due to the mechanical disadvantage experienced by the shoulders. These forces are typically exerted on the axilla, which is ill-suited for load bearing" (6). The MELA was designed to address the issue of reducing such forces and facilitating function for the end-user. The MELA demonstrated its ability to enhance elbow lock function, allowing subjects, in this study, to further use their prosthetic arm to assist in accomplishing various ADLs.

Even though the total number of subjects who participated in the clinical trials was small, it has been shown that "80% of the usability problems are detected with four or five subjects, additional subjects are less likely to reveal new information, and the most severe usability problems are likely to have been detected in the first few subjects. It has been found that the first 5 subjects tended to find about 85% of the usability problems uncovered by running 20 subjects. When separate curves are plotted for the problems rated high, medium, and low in severity, it can be seen that the problems judged to be more severe are more likely to turn up early in the evaluation" (8).

Resultant data have led to the following summation of the precommercial MELA:

Advantages

- Can be a viable assist for mechanical elbow lock control that offers both low force and small stroke to cycle any manual elbow

- Can act as a buffer between user and elbow lock which can help reduce breakage of elbow lock cable especially for active users who have a tendency to pull too hard on the cable
- Has potential to allow near-zero excursion on cable to operate
- With internal mounting arrangement, can improve cosmesis for the user
- Can be used with any single function momentary contact switch commercially available for prosthetic application.

Prescriptive Indicators

As a result of clinical trials, the MELA demonstrated that it can be beneficial for use by body-powered arm users with:

- Unilateral amputation
- Short AE (30 to 50 percent of acromion to epicondyle length) amputations
- Shoulder disarticulations
- Difficulty operating elbow lock control.

Disadvantages

- No mechanical backup in case of unit failure
- Slow operating speed (alternating response time)
- Necessary to unload the forearm in order to unlock the elbow
- Limited sensory proprioceptive feedback to the user
- Additional bulk when externally mounted on the surface of the upper arm
- Existing wiring and retaining clip were susceptible to breakage
- Noise level generated from the motorized gear-motor proved disturbing to some users.

Contraindications

The MELA, in its present configuration, would not be indicated for the following:

1. *Persons with bilateral AE amputations.* This is primarily due to the momentary hesitation between activation of the switch and the subsequent running of the motor drive to actuate the cable. This hesitation causes the MELA to function more slowly than a conventional mechanical system. A person with bilateral AE amputation who uses a figure eight harness system will experience loss of forearm position while the MELA hesitates. (Before the lock activates, the forearm will have extended a few degrees; thus, losing the position the user had selected). If this issue is resolved, then bilateral fittings could be considered.
2. *Persons who are experienced users;* unless alternating response time between locking and/or unlocking the elbow could be improved.
3. *Persons using a flail arm hinge elbow.* The hinge is located on the medial side of the prosthesis; the MELA would also be mounted on the medial side and would intrude uncomfortably into the axilla area.
4. *Persons with severe brachial plexus injury.*

RECOMMENDED MODIFICATIONS

1. *Incorporate a mechanical back-up system in case of unit failure.* The lack of a mechanical override is a problem for all persons with amputation, but more particularly for bilaterals. This poses a safety hazard and needs to be corrected.
2. *Increase existing operating speed (alternating response time).* Response time for alternating lock/unlock function was found to be too slow for experienced persons with amputation.
3. *Eliminate the need to unload forearm to cycle the MELA.* Some users experienced difficulty when attempting to unload the lock mechanism in order to unlock the elbow. In the presence of a load or pressure on the forearm, the MELA could not easily unlock the elbow. The power generated by the MELA to cycle the lock was felt to be insufficient by users and prosthetists. There needs to be a method available for the user to easily cycle the MELA in this situation.
4. *Improve sensory proprioceptive feedback to the user.* Existing body-powered arms provide the user with some mechanical feedback from the shoulder harness and cable-control system. It was difficult for the user to discern lock function when using the MELA.
5. *Wiring should be a heavier gauge and should be soldered in accordance with good soldering practice.* Wiring should be strain-relieved to prevent breakage at soldering locations and to improve durability.
6. *Dampen noise from gear motor.* Existing noise draws attention to use of the arm.

7. *Improve battery life between charges.* Present battery and charger required active users to recharge daily overnight.
8. *Improve durability of existing retaining clip.* During clinical trials, the clip snapped off on several occasions.

CONCLUSION

Based on the results of this multicenter evaluation, The MELA will require some modification for the commercial version. The primary issues focused on increasing operating speed (alternating response time); unloading forearm (sometimes required to cycle the MELA); providing mechanical backup in case of unit failure; reducing gear-motor noise; and improving the integrity of the wiring and retaining clip.

These particular issues have been brought to the attention of the President, and the Director of R&D of the Hosmer-Dorrance Corp. (precommercial model manufacturer). After discussion with NUPRL (developer), response from the manufacturer has indicated that resolution for most of these issues is readily achievable. The issue of increasing speed (response time) and unloading forearm will require more investigation and consumer feedback from the commercial market. Addressing these issues will only serve to enhance the performance, clinical application, and marketability of the MELA.

The modifications, as described in this report, are provided to guide this process and to further embolden the collaboration between the developer (NUPRL) and the manufacturer to resolve the identified technical issues and bring the MELA to market.

During the course of the evaluation, the following proposed marketing plan was provided to TTS:

1. Sell the MELA and the elbow as one unit, pre-assembled and ready for installation in a prosthesis.
2. Using Hosmer's central fabrication facilities, retrofit the MELA to an existing or new prosthesis.

A third option, which TTS pursued with Hosmer, is to have the MELA available as a stand-alone product. Hosmer has indicated that the MELA can be made into a kit for this purpose; allowing prosthetists experienced with electrically powered prosthetic components the opportunity to purchase the MELA for on-site installation.

Having several marketing options available, as described above, and allowing the local prosthetist sufficient leeway for customization, as needed, will only enhance the commercial success of the MELA.

A Product Evaluation Data Sheet will be completed by TTS and used for dissemination VA-wide.

Results of this evaluation demonstrated that the MELA has proven to be acceptable for use as an alternative control method for manual elbows. It can be considered for prescription for appropriate veteran beneficiaries. The MELA is recommended for commercial production.

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