Clinical Evaluation of the Modular Electromechanical Lock Actuator for Above-Elbow Prostheses: A Preliminary Report

Prepared by Mary E. Cupo, BS, KT, Health Science Specialist and Saleem J. Sheredos, BEE, MHCA, Rehabilitation Engineer, Program Manager, Technology Transfer Section, Rehabilitation Research and Development Service, Department of Veterans Affairs, Baltimore, MD 21202-4051

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 their experience with prostheses for persons with high-level, upper-limb amputations, developed MELA to provide users with more efficient, versatile control and operation of their existing, cable-operated, positive-locking elbow and wrist components. The design of MELA has advanced to the point where it has the potential to improve the functionality and effectiveness of existing, body-powered or manually positioned above-elbow prostheses. This R&D effort has resulted in a pre-market model that is now ready for the national field evaluation part of the technology transfer process coordinated through the VA Rehabilitation Research and Development Service, Technology Transfer Section.

Key words: body-powered above-elbow prostheses, high-level upper-extremity amputations, modular electromechanical lock actuator, technology transfer.

BACKGROUND

The mission of the Rehabilitation Research and Development (Rehab R&D) Service is to support an intramural program for improving the quality of life for veterans with disabilities. The program is committed to provide rapid transfer of rehabilitation research and development technology and dissemination of information into the VA medical health care system. The outcome promotes greater functional independence in the activities of daily living (ADL) for veterans with disabilities and contributes to the nation's knowledge about disease, disability, and rehabilitation.

One of the highest priority areas of the Rehab R&D Service involves prosthetics, amputations, and orthotics. The VA sponsors development in this area which results in artificial limbs that are lighter, fit better, are more comfortable, and permit the user more natural movement for ADLs and rigorous activities such as running, skiing, etc.

In keeping with the commitment to support the advancement of technologies within priority areas, the VA Rehab R&D Service sponsored 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.
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). It was the developer's belief that 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 a simple, modular, electromechanical lock actuator that can be used in conjunction with existing cable-operated elbows and positive-locking wrist components.

**PRODUCT DESCRIPTION**

MELA is a simple, modular, electrically powered lock actuator used in conjunction with existing cable-operated, positive-locking elbow and wrist components. The electromechanical lock actuator and the electronic circuit are powered by a single 9-volt rechargeable transistor battery. The device consists of a 10-mm diameter gearmotor driving a steel screw into a brass nut (Figure 2) (1). A steel cable is attached between the nut and the mechanical locking mechanism. The weight of MELA is 0.92 ounces (26 gm) and does not contribute significantly to the total weight of the prosthesis. Its overall length is 3 inches (76.2 mm). 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, thereby pulling the cable and unlocking the mechanism. The next activation extends the nut, releasing tension in the cable which allows the spring loaded mechanism to lock. Each activation alternates between locking and unlocking.

The drive components are encased in an anodized aluminum housing. The force produced by the drive nut is 7.2 lbf (32.0 N) minimum at stall with a total travel of 0.5 inches (12.7 mm). No-load speed is 1.0 inch/second (25.4 mm/second). The electrical control circuit is the NU 118D v2.3.

MELA's principal advantage 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 elbow.

**Figure 2.**
Typical mounting arrangements on Hosmer Dorrance E-400 elbow with either outside or inside cable exit (2,3).
AE prosthesis. A second advantage is that greater options are available for placement and configuration of the switch control over that possible with existing cable or lever controls (Figure 3).

**SUBJECT CRITERIA**

The two previously described advantages make MELA particularly suited for persons with high-level AE amputations (unilateral and bilateral). These individuals, due to the shortness or absence of a residual limb (or limbs), experience difficulty performing the necessary shoulder movements required to generate adequate cable excursion for complete prosthetic elbow and terminal device operation. As a result, the prognosis in terms of functional expectancy for these individuals is often poor, especially in cases involving ascending amputation of the arm(s) from approximately 30 percent of the humerus (humeral neck) through the shoulder joint (shoulder disarticulation) up to the most proximal level (forequarter), usually involving the removal of both the clavicle and scapula as shown in Figure 4 (4).

MELA can be used with any type of prosthetic socket. The developer has indicated the following criteria for screening appropriate subjects:

- Above-elbow, or higher, residual limb amputee prosthetic users who use body power and have difficulty operating their existing mechanical elbow lock—whether with a conventional harness, nudge control, excursion amplifier, or other alternative arrangement to assist in elbow lock control
- Prospective subjects may be either unilateral or bilateral amputees.

In addition, the developer states that there are no special prosthetic fitting methods required. MELA does not have to be modified to fit a particular situation. The developer feels that practitioners will prescribe MELA because of its potential to augment existing body-powered prostheses; thus providing improved functional expectations and increased independence for persons with high-level AE amputations (Figure 5).

**TECHNOLOGY TRANSFER PROCESS AND RESULTS**

Within the Rehab R&D Service, TTS provides a systematic progression of proven research findings
into clinical use, product manufacture, and commercial availability (Figure 6). This is accomplished, with collaboration from appropriate VA Central Office (VACO) Directors, by objective, multi-center clinical research evaluation studies. These studies validate the safety, reliability, effectiveness, and commercial readiness of prototypic technologies and techniques intended to optimize the independence and quality of life of veterans and nonveterans with disabilities. Successful results are transferred to the VA health care system and ultimately to the national health care system.

Research and development of the basic scientific concept for MELA resulted in a working prototype that underwent alpha testing with a bilateral high-level AE amputee. Results were encouraging and demonstrated a need to continue development toward a commercial product. A request for evaluation (RFE) was submitted to TTS to bring MELA into the Rehabilitation R&D Service’s technology transfer process.

The RFE is a screening process of research and development products and techniques to identify those that have reached a stage of accomplishment and are ready for consideration to enter the technology transfer program. Once the review process has been completed, and results are positive, a recommendation to proceed with a national, multi-center clinical study, with subsequent budget, is submitted to the Director, Rehab R&D Service. This approval commences the beta testing (evaluation phase) and manufacture of the precommercial models for initiating the technology transfer process.

The MELA project received positive RFE review and approval from the Director, Rehab R&D Service to proceed with the evaluation phase. A procurement contract for the manufacture of 12 precommercial models was awarded to the Hosmer Dorrance Corp. (Campbell, CA), which is committed to marketing MELA pending the outcome of the clinical trials. Throughout the evaluation phase, the manufacturer must demonstrate the ability to provide the necessary technical support of the product and is the primary consultant. The developer becomes a secondary consultant when and if the need for design changes becomes apparent from subject feedback and product performance.

With collaboration of the Director, Prosthetic and Sensory Aids Service (PSAS), VACO, TTS has coordinated subject selection per criteria established in the evaluation protocol.
DISCUSSION

This national, multi-center clinical evaluation is being conducted to determine the acceptance of MELA by the target population and to identify any modifications needed to improve optimal use of the device and to enhance its marketability. The following specific areas will be scrutinized in this evaluation:

- Prescription indications and contraindications
- Fitting (i.e., compatibility with existing body-powered AE componentry, use of existing versus special techniques, knowledge, tools, etc.)
- 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 arrangements 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.

During the course of the clinical trials, it may be necessary to freeze the process in order to make necessary design changes as a result of subject feedback. At this juncture, both the manufacturer and developer will collaborate to incorporate the changes. Once completed, the evaluation will resume with the revised models.

REFERENCES