

CLINICAL AND ECONOMIC IMPACT OF
UTILIZING MYOELECTRIC UPPER
EXTREMITY ORTHOSES IN THE VA
HEALTH SYSTEM

VHA Guidelines for Prosthetics

The Veterans Health Administration (VHA) Prosthetic and Sensory Aids Service (PSAS) is the largest and most comprehensive provider of prosthetic devices and sensory aids in the world providing care for over 50,000 individuals with major limb loss, including those with amputations secondary to combat. The VA classifies prosthetics as artificial limbs and any devices that support or replace a body part or function. The VA provides all clinically appropriate and commercially available, state-of-the-art prosthetic equipment and devices to Veterans across the full range of patient care.¹

In consideration of upper extremity prosthetics, the VA has published guidelines that address the key principles of rehabilitation and clinical care for patients with upper limb amputation. These guidelines provide detail including but not limited to the topics of perioperative assessment, pre-prosthetic training and functional training. According to guidelines, functional training aims to teach the patient to properly integrate use of the

According to guidelines, functional training aims to teach the patient to properly integrate use of the prosthesis to safely perform bimanual activities, maximize independence and reduce caregiver burden.

prosthesis to safely perform bimanual activities, maximize independence and reduce caregiver burden. Guidelines include a sample list of functional bimanual ADL and IADL tasks to help guide the therapist and patient through functional prosthetic training. Tasks are broadly grouped into categories such as feeding, dressing and hygiene with specific tasks listed for each.²

History of Myoelectric Devices

The first myoelectric prosthesis was created between 1944-1948 by Reinhold Reiter, a physics student at Munich University. Reiter recognized that to work properly, the device needed to obtain maximum information from the myoelectric signal.³ The technology has, over the past 50 years, moved from single muscle control of a single prosthesis function to more complex muscle group activity control of multifunction prostheses. Central to these changes have been developments in the means of extracting information from the myoelectric signal.⁴

Later work expanded the concept of myoelectric control to orthoses for upper extremity impairment. By supporting research in 1990, the VA promoted and inspired development for a future myoelectric orthosis that could be of benefit to Veterans that have upper extremity impairment.⁵ In 2006, work in myoelectric upper extremity orthoses at MIT was commercialized resulting in the development of the Myo-Pro myoelectric elbow-wrist-hand orthosis (MEWHO).

Myoelectric Prosthetics v. Myoelectric Orthoses

In comparing the clinical benefits of upper extremity myoelectric prosthetics to orthoses, the commonality involves the replacement of lost function due to either the absence of the limb (amputation) or, in the case of neuromuscular injury or disorder (stroke, ALS, spinal cord injury, traumatic brain injury, brachial plexus injury) inability to use the limb. Both device benefits can be compared across several categories as shown in Table 1.

Device	Limb Replacement	Limb Support	Perform ADLs	Safety	Emotional Health
Myoelectric Prosthetic Arm	•		•	•	•
Myoelectric arm orthosis		•	•	•	•

Table 1.

There is reasonable correlation between the myoelectric arm orthosis and the myoelectric arm prosthetic across several dimensions. As with prosthetics, the VHA has clear practice recommendations for provisioning of orthotics.

- Documented musculoskeletal or neurological condition in the medical record, which supports the use of an orthotic device.
- The Veteran (with or without the assistance of a caregiver) must be willing and able to wear and care for the orthotic device properly.
- A VA prescription is received from a competent/credentialed clinician requesting a specific orthotic device or requesting that a patient be evaluated by a competent/credentialed clinician for an orthotic⁶

Clinical and Economic Considerations for Myoelectric Orthoses

For those Veterans with a paretic arm due to neuromuscular injury, provisioning a myoelectric orthosis may have compelling clinical and economic implications. An examination of upper extremity paresis due to stroke helps illustrate this point although similar analyses are possible for other diagnoses (spinal cord injury, traumatic brain injury, brachial plexus injury, ALS, MS) that result in a paretic arm.

Post stroke treatment for hemiparesis typically consisting of physical and occupational therapy relies on clinical outcome metrics relative to weakness, loss of limb use, ability to perform ADLs and comorbidities associated with overuse of the unaffected side. These outcome metrics are summarized in Table 2.

Table 2.

	Weakness	Loss of arm/hand use	ADLs	Overuse of Unaffected Side	Safety	Emotional	Independence
Clinical	•	•	•	•	•	•	
Quality of Life	•	•	•			•	•

A MEWHO can be an effective treatment pathway as the device will support the weakened arm and range the elbow, wrist and hand through user intention. Clinically, this enables the performance of goal driven ADLs in the therapy clinic and home and may help to avoid overuse of the unaffected arm. Kim et al, reported significant improvements in arm impairment and self reported functional use of the arm from baseline to discharge during a 6 week home program using an EMG controlled, wearable elbow orthosis with stroke patients. Participants utilized the device to perform ADLs including sit to stand, holding a toothbrush, carrying a basket, opening and closing a refrigerator door and self feeding. No adverse events were reported.⁷ Qualitatively, the device could increase patient safety by enabling bilateral upper extremity support and function while contributing to overall well being by enabling the user to function more independently with the ability to perform functional tasks related to feeding, dressing and hygiene.

The economics of stroke treatment can be considered from both a short and long term perspective as shown in Table 3.

Table 3.

	Physical Therapy	Occupational Therapy	Acute Rehabilitation	Orthotics, other devices	Pharmacological	In-home care/nursing	Independence
Short Term	•	•	•	•			
Long Term					•	•	•

A MEWHO can be an effective treatment pathway as the device will support the weakened arm and range the elbow, wrist and hand through user intention. Clinically, this enables the performance of goal driven ADLs in therapy clinic and home and may help to avoid overuse of the unaffected arm.



Data indicate that the average year one cost for outpatient stroke rehabilitation services and medications, post inpatient rehabilitation discharge, at \$17,081. The corresponding average annual cost of medication is \$5,392, while the average annual cost of rehabilitation service utilization is \$11,689.⁸ The cumulative cost of stroke management through rehabilitation and medication is shown over 5 years in Table 4.

Cumulative Cost of Stroke Management

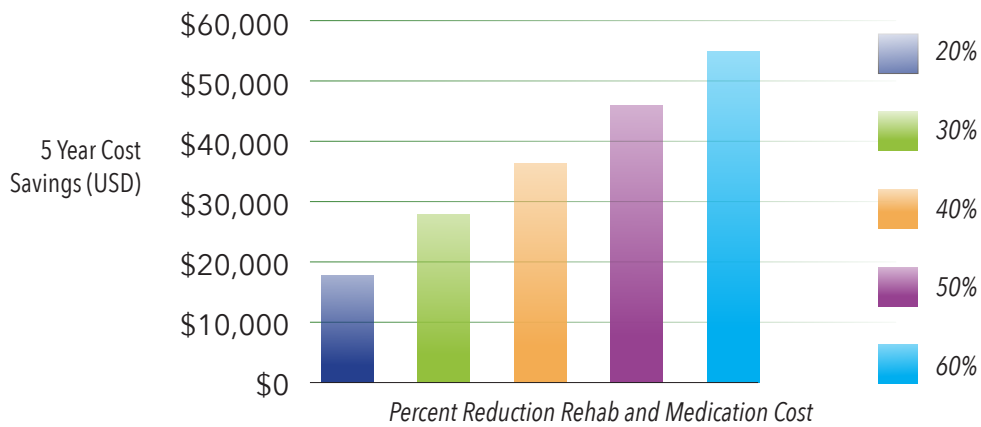
Table 4.

Year 1	Year 2	Year 3	Year 4	Year 5
17,081	34,162	51,243	68,324	85,405

It is likely the provisioning of a MEWHO could help mitigate cost due to stroke management as the device can provide ongoing movement of the paretic arm, effectively ranging the limb during functional use. This should reduce the need for ongoing rehabilitation and medication associated with inactivity. Estimated cost savings over five years to the VA as a percent of cost reduction are shown in Figure 1 and may range from 18,000 - \$45,000 over 5 years.

Cost Savings with Orthosis over 5 Years*

Figure 1.



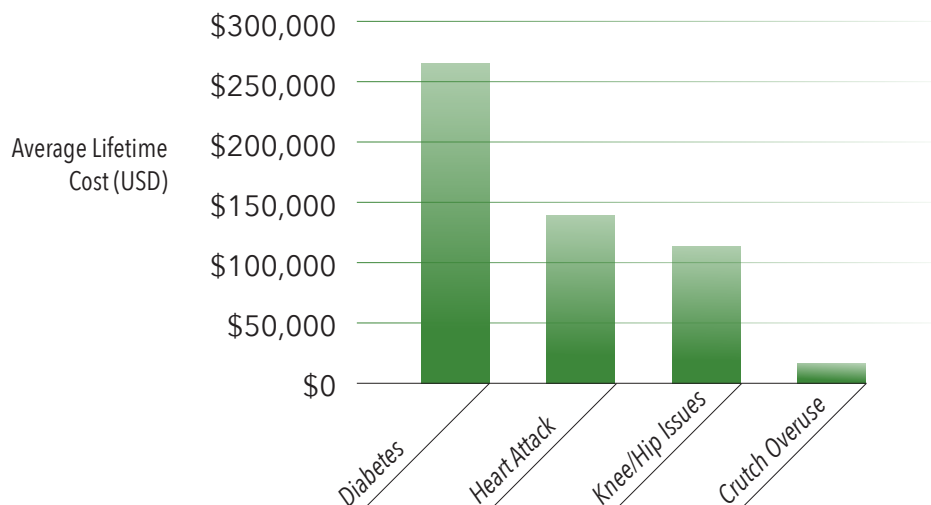
* Based on assumptions above.

Indirect costs not included in this estimate involve lost productivity, lost work years and cost to employers.

There is precedent in prosthetics for considering cost burden associated with inactivity. Without prosthetic care, many individuals will lead a more sedentary lifestyle which lead to secondary complications. The average lifetime cost of these complications are shown in Figure 2. Many of these lifetime costs average well over \$100,000.⁹

Average Lifetime Cost of Secondary Complications in the Absence of Prosthetic Care

Figure 2.



The MyoPro Myoelectric Orthosis

A commercially available MEWHO is the MyoPro Motion-G from Myomo, Inc. The device is custom fabricated and designed to be used in the home to increase functional ADLs by providing the user with intention driven, myoelectric elbow and hand movement and manual wrist articulation. Examples of functional tasks being performed with the MyoPro are shown in Figure 3. Not all hemiparetic Veterans are candidates. The general inclusion criteria are:

- Inability to use affected arm(s) functionally, inability to open/close hand
- Minimum of trace MMT (1/5) in Biceps and/or Triceps (i.e. good volitional EMG signal)
- Full passive range of motion in elbow, wrist and fingers
- Intact cognition (mini-mental score > 20)
- Tone should be mild-moderate (score up to 3 on Modified Ashworth Scale)
- Good caregiver/family support
- Highly motivated
- Active shoulder flexion of *at least* 30-40 degrees or shoulder abduction of at least 20 degrees



Conclusion

There are a number of similarities between myoelectric prosthetics and myoelectric orthoses including clinical and economic benefit as well as specific provisioning guidelines within the VA Health System. A myoelectric upper limb orthosis can be supplemental to current treatments for stroke and other neuromuscular injuries/disorders. These devices can provide clinical value when surgery and therapy cannot restore upper limb function to the degree that the arm will be useful for performing functional tasks, including eating, cooking, dressing and carrying objects. The orthosis may also offer economic benefit in its ability to reduce costs associated with rehabilitation and medication. Additional economic benefit may result through improved safety (increased balance can reduce the potential for falls), improved outlook and emotional well being (can reduce the need for medication) and increased independence (can reduce the need for in-home care because of increased functional capability with the device).

MYOELECTRIC ORTHOSIS CLINICAL & ECONOMIC VALUE

	Perform ADLs again	Prevent overuse of sound side	Reduce need for therapy/meds	Improve Outlook	Independence	Safety
Clinical	•	•	•	•		
Economic			•	•	•	•

Eating



Mobility



Balance & Safety



Figure 3.

References

1. Department of Veterans Affairs, ASoC Fact Sheet, May 2015 Department of Veterans Affairs, PSAS Fact Sheet-Benefits, January 2016
2. VA/DoD Evidence-Based Clinical Practice Guideline for the Management of Upper Extremity Amputation Rehabilitation, Version 1.0, 2014
3. Proceedings of the 1992 MyoElectric Controls/Powered Prosthetics Symposium Fredericton, New Brunswick, Canada: August, 1992. Copyright University of New Brunswick.
4. P. Parker, , K. Englehart, B. Hudgins 2006 ISEK Congress Basmajian Lecture, Myoelectric signal processing for control of powered limb prostheses
5. Nisim Benjuya, Ph.D., Steven B. Kenney, B.S.M.E., Myoelectric Hand Orthosis, JPO, Vol 2, Num 2, 1990, p 149. This work was supported by the Veterans Administration RR&D Service
6. VHA Prosthetic Clinical Management Program (PCMP) Clinical Practice Recommendations for Prescription of Orthotic Devices, May 5, 2004
7. Kim GJ, Rivera L, Stein J, A Combined Clinic-Home Approach for Upper Limb Robotic Therapy after Stroke: A Pilot Study, Archives of Physical Medicine and Rehabilitation, Dec 2015, 96(12): 2243-8.
8. Godwin KM, Wasserman J, Ostwald SK., Cost associated with stroke: outpatient rehabilitative services and medication, Top Stroke Rehabil. 2011 Oct;18 Suppl 1:676-84.
9. Prosthetic Coverage: Saving Money and Saving Lives, Amputee Coalition of America White Paper. Online reference: <http://www.hangerclinic.com/new-patient/Documents/prosthetic-coverage-saving-lives.pdf>.

Myomo, Inc.

One Broadway, 14th FL

Cambridge, MA 02142

(877) 736-9666

info@myomo.com

www.myomo.com