CONSENSUS CLINICAL STANDARDS FOR THE PROSTHETIC MANAGEMENT OF UNILATERAL TRANSRADIAL AMPUTATION

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ABSTRACT

Consensus clinical standards of care were recently developed through three rounds of Delphi consensus surveys. The 40 statements that reached consensus standards for inclusion encompassed indications for general prosthetic consideration, as well as indications and considerations for body powered, externally powered and oppositional silicone restoration prostheses, terminal device selection, the selection of body powered control strategies, considerations for moisture, debris or heavy duty use, activity specific prostheses and indications for multiple terminal devices. These standards may serve to guide clinical decision making and inform medical policy.

INTRODUCTION

While substantially less common than major lower limb amputation, major upper limb amputation accounts for approximately 16% of the major limb loss affecting an estimated 2.2 million Americans.[1] While clinical practice guidelines have been developed for the broad holistic care of the individual with upper limb amputation or limb deficiency,[2-3] there has been an absence of detailed clinical guidance with respect to prosthetic management. A relatively recent multi-disciplinary State of the Science Conference, held by the American Academy of Orthotists and Prosthetists addressed design options for upper limb prostheses. The Conference concluded that those rehabilitation professionals that have amassed considerable experience in working with upper limb amputation and limb deficiency should be recognized as the most informed source of currently available evidence.[4]

Recent years have seen the emergence of a number of clinical practice guidelines based on the published evidence and addressing prosthetic patient populations. These have included post-operative care, prosthetic foot selection, transtibial socket design and prosthetic knee selection.[5-11] When the published evidence for a given episode of care is limited, the highest level of available evidence is collaborative consensus from subject matter experts, with the Delphi process being commonly employed.[12] Several such guidelines have been performed and disseminated within the field of prosthetic rehabilitation.[13-15] The use of Delphi consensus techniques in prosthetic and orthotic rehabilitation has been summarized via systematic review with a number of best practice recommendations.[12] The purpose of this abstract is to summarize the methods and findings of a recently published Delphi consensus exercise to establish clinical care standards in the prosthetic management of individuals with unilateral transradial amputation or limb deficiency.[16]

METHODS

The full details of the methodology associated with these consensus guidelines has been published elsewhere[16] and can be summarized as follows. Project directors from a national provider of upper limb prosthetic rehabilitation met with a focus group of experienced upper limb clinicians to review available systematic reviews in the area of upper limb prosthetic rehabilitation and identify postulates related to the indications, contraindications, and considerations associated with prosthesis type (e.g., body powered vs externally powered) and terminal device type (e.g., hand vs hook) with regard to unilateral transradial prosthetic management. These initial postulates (n=40) were then entered into a secured, web-based survey platform. A panel of 20 certified prosthetists, each of whom oversaw the care of at least 85 new upper limb prosthetic cases per year, and two occupational therapists, both of whom treated at least 75 upper limb prosthetic patients annually, anonymously considered each postulate, rating their degree of

agreement or disagreement with each and providing clarifying or qualifying statements to explain their position. The panel was geographically diverse with an average of 21 years of clinical experience.

Consensus standards for the acceptance of a clinical postulate was predefined at 80%. Those postulates that exceeded this threshold were retained within the clinical consensus standards. Those that did not were assessed by the project directors and amended to reflect the comments from the Delphi survey panel. Amended postulates where returned to the panel for subsequent review and potential acceptance. A total of 3 rounds of anonymous surveys were administered. In the first round of surveys 31 postulates were accepted by the panel with 9 postulates failing to reach the consensus threshold. Eleven of fourteen amended postulates were accepted in the second round. A final postulate was presented and accepted in the 3rd survey round.

RESULTS

Once the survey rounds were concluded and consensus postulates were determined, they were aggregated by the following topic areas for ease of integration into clinical practice

Prosthetic Candidacy

Candidacy for a prosthesis may be based upon functional need, psychosocial considerations or preservation of the contralateral extremity. A prosthesis should be considered for an individual with unilateral transradial amputation or limb deficiency when any of the following is identified: An individual is unable to accomplish self-care activities or ADLs independently; an individual has functional, vocational, or avocational needs that cannot be met without a prosthesis; the person's psychosocial acceptance of their amputation/limb deficiency would be improved by the use of a prosthesis; or an individual is at risk of overuse syndromes on their sound side.

Body Powered Prosthesis Candidacy

There are a number of considerations that should be assessed prior to the recommendation and provision of a body powered prosthesis. These include patient education and awareness as well as certain physical attributes. Patients should fully understand the restriction, associated pressures and donning and doffing requirements associated with a control harness and be able to physically tolerate those elements. In addition, they should accept and understand that activities requiring dynamic prehension will be predominantly performed with a hook, rather than a hand. With regard to physical presentation, a patient's residual limb must possess adequate soft tissue coverage and integrity to allow cyclical loading of the limb within the prosthesis as experienced during cable activation of the terminal device. This tolerance may be facilitated with appropriate interface materials or socket design. Similarly, patients must possess adequate soft tissue coverage and integrity over those body segments underlying the control harness of the prosthesis. Finally, candidates for a body powered prosthesis must possess adequate strength and range of motion to generate the necessary cable force and excursion to actuate their terminal device.

Externally Powered Prosthesis Candidacy

Prior to the recommendation and provision of an externally powered prosthesis the following elements should be evaluated and considered. The candidate should possess adequate control input to control an externally powered prosthesis through EMG, FSR, electronic switch or linear transducer and understand and accept the noise, weight and charging requirements associated with an externally powered device. An externally powered prosthesis should be considered when one or more of the following is identified: A candidate lacks the strength or range of motion required to generate the necessary cable force or excursion for a body powered prosthesis; A candidate lacks the necessary soft tissue coverage and integrity to allow cyclical loading of the limb within the prosthesis, even with appropriate interface materials and socket design; a candidate anticipates the need for sustained, high grip strength through movement; a candidate's functional work envelope cannot be confined primarily to the area immediately in front of them; there is a compromise to gross body movements of the shoulders or back and/or an existing neurological compromise to the sound side upper limb (such as pain, numbness, or tingling); or a candidate has been previously fit with either an oppositional or body powered prosthesis and could not integrate it fully into their desired ADLs or vocational responsibilities, either because of mechanical constraints or psychosocial rejection.

Oppositional Silicone Restoration Prosthesis Candidacy

An oppositional silicone restoration prosthesis (sometimes termed "passive" or "aesthetic" prosthesis) should be considered when the user's primary priority is an aesthetic restoration of their forearm and hand, the user fully

understands and accepts the absence of active prehension, and the user fully appreciates the cosmetic limitations of an oppositional prosthesis.

Terminal Device Selection

Non-anthropomorphic hook-type terminal devices should be considered when enhanced visibility and find motor dexterity during object manipulation are desired and the user of a body powered prosthesis required a durable terminal device. Alternately, hand-type terminal devices should be considered when the associated psychosocial acceptance of an anthropomorphic terminal device is indicated for the patient, and the cosmetic and fine motor dexterity limitations of such terminal devices are fully understood by the patient.

Body Powered Control Strategies

Users of body powered prostheses will need to actuate their devices using either the more common voluntary opening strategy or the less frequently utilized voluntary closing strategy. The former should only be considered when the user presents with adequate strength to overcome the mechanical resistance mandated by the necessary grip strength of the terminal device and fully understand and accepts the relationship between available grip strength and the strain experienced through the harness during operation of the terminal device. Similarly, the voluntary closing control strategy should only be considered when the user understands and accepts the potential energy expenditure and cognitive load associated with sustaining grip strength through range of motion.

Moisture, Debris and Heavy Duty Use

With the recent improvements in certain externally powered components, appropriately designed body powered and externally powered prostheses can be considered when exposure to moisture, debris or heavy duty use is anticipated.

Activity Specific Prostheses

Activity Specific Prostheses should be considered when the user's needs during a give activity exceed the capabilities of alternate prosthetic designs and/or terminal devices.

Multiple Prostheses

Multiple prostheses or terminal devices may be indicated when the user's needs exceed the capabilities of a single prosthesis type or terminal device.

DISCUSSION

The aim of this effort was to establish treatment guidelines for the prosthetic management of unilateral transradial amputation and limb deficiency. While a degree of subjectivity is innate to Delphi consensus methodology our protocols were consistent with those used in prior Delphi consensus efforts in the field and recommended best practices.[12] This included initial postulate generation based on available evidence, the selection of a highly knowledgeable and experienced expert panel of an appropriate size, attainment of a high response rate, *apriori* establishment of a high standard of consensus and the use of multiple rounds of surveys to refine postulates towards consensus acceptance.

The Delphi processes facilitated the establishment of clinical practice standards for the prosthetic management of individuals with unilateral transradial amputation in the absence of strong, detailed evidence from existing clinical research and systematic literature reviews. Many clinicians lack the necessary expertise in the area of upper limb prosthetic management to allow a high degree of confidence in treating this population towards optimal clinical outcomes. These clinical care standards may help inform clinical decision-making processes to ensure that essential elements are taken into clinical consideration. However, they are not so prescriptive as to preclude the individual judgment of the clinician or the values and preferences of the patient. These consensus standards have also been welcomed by medical directors and policy makers in addressing the void that would otherwise be present in the prosthetic management of this relatively small patient population.

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