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PRELIMINARY FEEDBACK FROM FIELD TRIAL USERS OF THE MOTION CONTROL MULTI-FLEX WRIST

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ABSTRACT

The feedback provided by patients in the early development of components is essential to the transition of new components into mainstream production and ultimately the success of the new components. This feedback often allows the manufacturers to perform essential design changes to the product to improve durability and function. The Multi-flex (MF) wrist is a compliant prosthetic wrist unit that features both locking positions and spring assisted resistance. This article reports on information gathered from questionnaires on the Motion Control MF wrist during a recent field trial. This article will address the features of the MF wrist, data collected from preliminary field trial questionnaires and the activities of daily living performed by a single user while using the MF wrist.

INTRODUCTION

Field trial testing prior to commercial release of new products is an essential aspect of product development in upper extremity prosthetics. The subject of this article is the Multi-flex (MF) wrist manufactured by Motion Control. This paper will specifically address the features of the MF wrist, field-trial questionnaires collected from four subjects using the MF wrist and a single subject demonstrating his work related job activities.

Research papers written about hand use in performing everyday and occupational activities have shown the importance of wrist motion. Studies incorporating many different tasks noted a requirement of 80 degrees for wrist flexion and extension and 60 degrees for radial and ulnar deviation. When eating, 30 degrees of flexion and 30 degrees of radial and ulnar deviation were needed (1). Wrist motions are essential to everyday tasks and work related activities. Current prosthetic technology only incorporates variable wrist flexion and extension with a series of locking positions and friction based radial and ulnar deviations.

The MF wrist is directly bolted to the specific Motion Control terminal device (i.e., a hand or electric terminal device, “ETD”). The MF wrist affords many different passive as well as locking positions. The basic joint in the MF wrist is a universal joint. The universal joint has a spring assist to center the terminal device (TD) and provide resistance in flexion, extension and radial and ulnar deviation in the unlocked position. The MF wrist locks in one axis at neutral and at the extremes in both directions allowing locking in 28 degrees of flexion and extension. Since the MF wrist only locks in one axis, the user will have to select which axis the hand locks in during the initial ordering and installation of the MF wrist. The unlocked axis allows the same 28 degrees of range in ulnar or radial deviation with spring resistance return to neutral. Initially the MF wrist only locked at the extreme ranges of motion. However, due to field trial user suggestions it now has a neutral locking position. The MF wrist, and seal membrane is depicted in Figure 1. The seal membrane itself was an improvement made to the wrist after information gathered from field trials. The seal membrane keeps the mechanism cleaner, drier and protects the life of the springs.

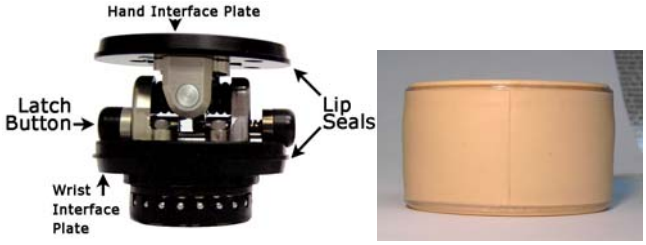

Figure 1: Depicts a close up view of a) MF wrist, latch button and lip seals and b) seal. The latch button engages or disengages the locking mechanism. Proximal and distal lip seals were created to allow the donning of a flexible membrane. This membrane minimizes debris, and moisture entering the MF wrist unit.

Figure 2: Depicts the overall length using an MF wrist compared to the standard hand and ETD

The size and weight comparison for the standard hand and ETD compared to terminal devices utilizing a MF wrist are represented in Table 1. The weight differences noted between a hand and an ETD are due to extra spacers necessary to allow full locking at extreme ranges.

Device	**ETD Std**	**ETD w/ MF**	**Hand Std (sz 7 ¾)**	**Hand w/ MF**
Weight	15.2 oz	17.5 oz	16.9 oz	18.1 oz
Length	6 ¾ in	7 5/8 in	6 in	6 3/8 in

Table 1: Weight differences between the standard hand and ETD, with and without the MF wrist unit.

QUESTIONNAIRES

Upper extremity is a very small patient population; therefore it is often difficult to have large number of field trial participants. Participants for this field trial were selected based on the following criteria: experienced user of an externally powered prosthesis; powered arm is functioning and getting at least 5-10 hours per day use; good communication skills. Although the number of subjects participating is very small, and statistically the data gathered is insignificant, the scope of the information gathered from these field trial users helps guide development and design improvements as well as validates that the design parameters are met.

The questionnaires were administered via telephone from Motion Control. The telephone calls were administered in this fashion so that the questioning could be open-ended and the caller could explore functional areas that a written form may not be able to gather. The ultimate goal of these field trial questionnaires is to gather field trial user feedback to improve function and durability of the product. Any questions about how the wrist is being used in a specific task could be further explored more easily with a phone call discussion.

There were a total of four subjects participating in the field trial tests. The average number of month’s usage of MF wrist prior to administration of the questionnaire was 7 months. The amputation level, side of amputation, TD using the MF wrist and date the MF wrist was received by the field trial users are represented in Table 2.

	Subject 1	**Subject 2**	**Subject 3**	**Subject 4**
Amputation level	Long Transradial	Long Transradial	Transhumeral	Transhumeral
Side of amputation	Right	Left	Right	Right
Terminal device using MF	MC hand	MC ETD	MC ETD	MC hand

Date received MF	June 2005	June 2005	January 2006	June 2005

Table 2: Information about the MF wrist field trial users.

The subjects were asked to rate themselves on what type of prosthetic user they are. Three of the four subjects classified themselves as heavy duty users, while one identified themselves as medium user of prosthetic devices. The average hours the subjects reported wearing their prosthesis on a work day is approximately 14 hours per day. On a typical non-work day, the average wear time for their prosthesis was around 12 hours.

The subjects were asked questions relating to the percentage of time they wear the MF TD, percentage of time the MF is unlocked, and percentage of time the MF is locked in flexion or extension, see Table 3. Many of the subjects reported that they prefer to keep the MF in an unlocked position and cited locking the MF wrist only for lifting objects and tool handling. Since the MF wrist utilizes spring assisted return and resistance, many subjects discovered during the field trial usage a desire to have a stronger spring resistance. This suggestion was incorporated in later design improvements. The overall design was improved and simplified to make it easier to replace the springs as well as to install the cover.

	Subject 1	**Subject 2**	**Subject 3**	**Subject 4**
What % are you wearing MF TD?	81-100%	Response not marked	81-100%	81-100%
What % is the MF unlocked?	81-100%	81-100%	81-100%	81-100%
What % is the wrist locked in flexion or extension?	Prefers to keep unlocked	0-20%	0-20%	0-20%

Table 3

The subjects were asked to rate the comfort of the prosthesis compared to previous prostheses. This question was formulated with the idea that creating compliancy with in the wrist could minimize the forces transmitted to the socket making the socket more comfortable. Two of the four rated the comfort as “much better”, one rated as “better” and the last one rated as “about the same”.

The subjects were asked to rate picking up large objects. Three of the four rated this task as worse utilizing the MF wrist. Since the wrist only locks in one axis and the other remaining axis utilizes spring assisted resistance. Holding large objects causes the MF wrist to ulnar deviate.

The subjects were asked to rate ease in performance of tasks. All of the subjects reported “much better” in ease of performance of tasks with the MF wrist. The subjects were asked to rate the naturalness of using the prosthesis. All of the subjects responded with “much better” in the naturalness of using the prosthesis. Each subject rated the overall usefulness of the MF wrist as “much better” as well. All of the subjects reported that the MF wrist allows them to use the prosthesis for more activities. All subjects reported that the MF wrist allows for more grasp than stabilizing. Subjects indicated that tasks where the MF wrist seemed more useful were: handling a knife and fork, riding motorcycles, handling farm sprayer joystick controls more comfortably over longer periods, holding materials down, handling lighter objects such as a can of pop, opening doors, handling kids, driving one handed, holding tools in previously difficult to manage positions, rowing a boat, nailing and handling a fishing reel. Subjects used the MF wrist in the flexed position to pick up heavy objects, ride 4-wheelers, work on small parts in the workshop, cut vegetables in the kitchen, put on a scarf and hold stops in place. Subjects reported advantages of the MF wrist to be more natural, more comfortable, easy to orient for stable grasps and requires less adjustment of position. Disadvantages were reported as accidental locking of

the wrist, unstable when lifting heavy objects, takes time to lock, there is no lock in neutral (corrected through field trial feedback) and cuts gloves.

CASE STUDY

RD is a 32 year old male that sustained a work related injury to the left arm in 2003. The injuries necessitated a right, short transhumeral amputation approximately 3 1/2 inches distal to the axilla level (see Figure 3). Over the course of rehabilitation the subjects residual limb has necessitated several revision surgeries to try and ameliorate pain issues, relieve adherent scarring distally and provide better soft tissue coverage on the distal end of the residual limb.

RD continues to remain active on his family’s large crop and cattle farms. He drives large fertilizer (Figure 4) and sprayer vehicles (Figure 5) as well as four wheelers, repairs farm machines in the workshop, and uses drill presses and hand tools (Figure 6). He reports that the compliancy of the MF wrist has improved the comfort of his prosthesis over the course of a day.

Figure 3: Patient’s short transhumeral residual limb characteristics.

Figure 4: Fertilizer vehicle used on the farm. Many of the hand controls found in farming vehicles are located on the right side of the vehicle.

Figure 5: Sprayer vehicle utilized with an average sitting time of about 5 hours. The compliancy of the wrist as reported by the subject has improved his overall comfort while perform work related tasks over the course of the day.

Figure 6: Workshop activities performed to aide in maintenance of farm equipment.

SUMMARY

To fully quantify and understand the user aspects of this wrist a more comprehensive study would need to be performed. However user feedback in the early development of new products is essential in evaluating design goals as well as making design changes that ultimately improve the product prior to commercial release. From the information gathered from the field trial questionnaires we have learned that the users typically preferred to utilize the MF wrist in an unlocked position for 81-100% of the time. They also reported that the ease of performing tasks was improved. Overall comfort of the prosthesis while performing activities was also reported, which may have resulted from the use of a compliant wrist. In summary information gathered from the field trial users aided to improve the design of the MF wrist making it more functional and durable.

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