Active Powered Prosthosis (APEX) for Spinal Cord Injury

Protocol #6100003-100 Rev A
Study Sponsor: AbiliTech Medical Inc. & The National Institutes of Health (R43HD094440)

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Protocol Synopsis

Introduction

The Active Powered Prosthesis (APEX) (AbiliTech Medical Inc., Minneapolis, MN) is a proof-of-concept shoulder-elbow-wrist prosthesis device intended to provide non-invasive active powered robotic assistive movement to the upper extremities. In September 2017, the National Institutes of Health approved and funded the development of the APEX device through a Phase I SBIR Grant. (1R43HD094440-01). The APEX device is designed for users with upper level cervical spinal cord injuries and motor impairment of their upper extremities. AbiliTech Medical has a history of developing upper extremity prosthesis devices. The AbiliTech Assist device is an upper limb passive powered lift and assist device planned for release in Q3 2018. The APEX device represents an advancement from the AbiliTech Assist device by providing active power sources to lift and rotate the upper limbs. The increased range of motion provided by the APEX device will expand the activities of daily living (ADL's) for users of the APEX device.

Study Objectives

Objectives:

Perform focus groups with subjects and clinicians to evaluate a proof of concept active powered prosthosis.

1. Perform a focus group with three to six individuals with chronic tetraplegia to evaluate the user control interface of an active powered prosthesis device proof-of-concept prototype. Subjects will provide feedback on the device function and usability after manipulating the device on a mannequin.
2. Perform a focus group with Courage Kenny Research Institute Clinicians to validate device safety features, performance and assess the potential clinical utility of the device.

Primary Outcomes:

The following will be assessed:

1. User ability to control APEX device to manipulate objects in space
2. User ability to control APEX to move an object in a preferred pathway
3. User ability to control APEX device to push buttons
4. User ability to control APEX to lift a phone
5. Evaluate subject reported outcomes within their interaction with the APEX device through interviews and a survey

Secondary Outcomes:

1. To observe and assess any uncontrolled device guided movement during the APEX device testing on mannequin
2. Gain clinician feedback on device safety control mechanisms

Ancillary Data:

1. Subject Acclimatization/ Learning Time to Operate the APEX Device
2. Characterization of focus group population:
    a. Medical History: Diagnosis, level of injury, AIS classification; MMT Scores (shoulder, elbow, forearm, hand)
3. Feedback on device design
4. Feedback on user input control system

Study Design/Subject population

The study design will be that of a single arm pilot testing study with three to six study subjects (n=3-6). Target user population will be human subjects with spinal cord injury at levels C3 to C5, and ASIA Impairment Scale (AIS) A, B, or C. Inclusion and exclusion criteria are summarized below:

3.1 Inclusion Criteria:

1. Spinal cord injury at levels C3 to C5, and AIS A, B, or C
2. Greater than 3-months post injury or surgery to spinal column, arms, or shoulder
3. Ability to provide informed consent
4. Age 18 or over
5. Selected for participation based on investigator discretion

3.2 Exclusion Criteria:

1. Unable to follow instructions
2. Exhibit significant behavioral problems or impaired cognitive ability
3. Inability to provide consent
4. Non-English speaker

Clinicians involved in overseeing the device manipulation portion of the study will be expected to provide feedback about the APEX device.

Recruitment Process:

After IRB approval, subjects with upper extremity spinal cord injuries will be recruited through:

1. An internal search of subject records within Courage Kenny Rehabilitation Institution performed by an out-patient care coordinator.
2. This pilot study will be posted and listed on www.clinicaltrials.gov with contact information available for possible enrollment in the study. Due to the size (n=3-6) of this study and recruitment methods, issues with recruitment of subjects is not anticipated.

In-Clinic Evaluation

There are two components to this study:

1. Visit 1: User Focus Group:
    a. Consent/Subject Evaluation
    b. Study participant Body Measurements
    c. Device Testing
    d. Focus Group Discussion and Feedback
2. Visit 2: Clinical Focus Group:
    a. Presentation of Results
    b. Clinical Discussion

The duration of time between visits 1 and 2 is expected to be 2-4 weeks. User focus group participants will receive a $50 Visa gift card after completion of all study activities.

Evaluation of Outcomes

Primary and secondary outcome measurements will be recorded during the study to assess and validate the device feasibility for function and safety. Data will be collected and reported without statistical analysis. This study is designed to assess early feasibility and prepare for a larger clinical study in the

future. Primary functional and safety outcomes will be compiled and reviewed to assess the performance of the APEX device in meeting the requirements of SCI subjects. Pilot Study results and conclusions on performance will be provided by AbiliTech Medical and Allina investigators.

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1. Introduction

1.1. Disease Background

Spinal cord injuries (SCI) cause costly and morbid chronic conditions such as lack of voluntary movement, increased chance of pressure sores, problematic spasticity, loss of bowel, bladder, and sexual function, and more physical impairments which result in a lower quality of life and lack of independence. Approximately 285,000 people in the U.S. have SCI with approximately 17,000 new subjects added each year [1]. It is recognized that 54% of SCI's are cervical injuries resulting in upper extremity neuromuscular motor impairment [2]. Through a published survey, 48.7% of quadriplegics indicated that regaining arm and hand function would be the preferred treatment to improve quality of life [3,4].

While there are no treatments that reverse all morbidities of SCI, cellular research, spinal cord stimulation, and advanced high-intensity fitness regimens show promise in treating the effects of SCI and improving independence and quality of life [5,6,7]. Remarkably, subjects with AIS A or B injuries, defined as "complete" motor and sensory loss and "incomplete" with sensory but not motor function, respectively, have shown improvement in motor scores after 6 months with structured exercise (20). Moreover, advances in independence have been shown in subjects with complete injuries after year-long rehabilitation programs (22). These, and studies on orthotics and exoskeletons used to improve strength and neuromuscular health have focused mainly on the lower extremity (1-4) and restoration of lower extremity function on improving independence in activities of daily living (ADLs) in subjects with cervical SCI (6).

Recent advances in upper extremity orthotics with devices such as a mobile arm support, WREX, Armeo Robotic Arm Trainer, MyoPro, and the Swedish arm support have led to strengthened upper extremities and improved independence in activities of daily living (ADLs) of those with cervical SCI [14,15,16]. They are limited by cost, size, comfort, weight, and functionality [14]. Another important limitation is that many of these devices focus on in-clinic rehabilitation and limit the frequency of rehab opportunities and insurance coverage. Recent studies have shown a significant correlation between high frequency of rehab sessions and improved outcomes [7,17,18].

1.2. AbiliTech Medical APEX Background

The Active Powered Prosthosis (APEX) is a portable upper extremity prosthesis device that helps users with upper extremity motor impairment move their upper extremities through active robotic assistance. The device is controlled through body motion activation (i.e.: a body mounted 9 degree of freedom accelerometer sensor that is wirelessly connected to the device to interpret the user's movement into upper extremity assisted movement). The APEX device body chassis is worn by the user and has onboard processing, power, motors, sensors, and cables attached to the motors . Cables attached to the motors will extend throughout the body chassis to enable actuation of the user's upper extremities. The APEX is designed for optimal subject safety including mechanical, electrical and software stops to prevent uncontrolled device movement and injury to subjects.

Arm movement is activated and controlled by the APEX control system (ACS-III) consisting of body mounted movement control inputs and sensors, an on-board processor, sensors, motors, and firmware. While the APEX mechanical design is the initial concept model, the ACS III control system represents a third-generation control and data collection design. User directed control inputs will be

body motion activated, sensors will be placed on the head and/or combination of a head mounted joystick and buttons.

This is a first of its kind proof-of-concept model using a mobile Bowden-Cable robotic system to mobilize the upper extremity. A similar published research device called the CAREX [19] has demonstrated proof-of-concept but is stationary and has limited data on its use.

AbiliTech Medical has experience in developing similar devices. The AbiliTech Assist and the Hand Grip glove, funded by the State of Minnesota Spinal Cord and Traumatic Brain Injury Research Grant Program, are devices currently in development by AbiliTech Medical. The AbiliTech Assist is a hybrid power device. Motors power (active) the compression or relaxation of multiple arm and shoulder springs (passive) to provide lift and assist for users with reduced upper extremity mobility. The AbiliTech Hand Grip System, uses motors and cables to help users grasp and hold different objects and is similar in cable driven architecture to the APEX device. The APEX device will be a third-generation device leveraging the design architecture eg. ACS-III and clinical learning experience.

1.3. Other Similar Devices

To date, there are no mobile devices available that provide shoulder-elbow active motion assistance to individuals with upper extremity motor impairment. There are similar devices, such as the Hocoma Armeo® Power which assists with shoulder elbow and wrist movement and diagnosis and the MyoPro, which is mobile but only provides elbow and griping assistance.

1.4. Study Rationale

Currently there are no effective mobile devices that enable people with limited upper extremity movement to move their upper extremities, especially for individuals with upper level SCI (C1-5). This

severely limits independence, reduces the ability for individuals with this condition to complete ADL's and makes them dependent on caregivers to complete all physical interactions with their environment. We hypothesize that the APEX device can safely enable and control shoulder-elbow movement to improve ADL performance and independence. Individuals with upper level cervical spinal cord injury that have lost functional use of their arms have a high potential to increase their quality of life by using this device which justifies observing their interaction with the APEX Focus Group.

2. Objectives

Objectives:
Perform focus groups with subjects and clinicians to evaluate a proof of concept active powered prosthesis.

1. Perform a focus group with three to six individuals with chronic tetraplegia to evaluate the user control interface of an active powered prosthesis device proof-of-concept prototype. Subjects will provide feedback on the device function and usability after manipulating the device on a mannequin.
2. Perform a focus group with Courage Kenny Research Institute Clinicians to validate device safety features, performance and assess the potential clinical utility of the device.

Primary Outcomes:
The following will be assessed:

1. User ability to control APEX device to manipulate objects in space
2. User ability to control APEX to move an object in a preferred pathway
3. User ability to control APEX device to push buttons
4. User ability to control APEX to lift a phone
5. Evaluate subject reported outcomes within their interaction with the APEX device through interviews and a survey

Secondary Outcomes:

1. To observe and assess any uncontrolled device guided movement during the APEX device testing on mannequin
2. Gain clinician feedback on device safety control mechanisms

Ancillary Data:

1. Subject Acclimatization/ Learning Time to Operate the APEX Device.
2. Characterization of focus group population
    a. Medical History: Diagnosis, level of injury, AIS classification
    b. Subject examination: MMT scores
3. Feedback on device design
4. Feedback on user input control system

3. Trial Population

Target user population will be three to six individuals with spinal cord injury at levels C3 to C5, and AIS A, B, or C. Inclusion and exclusion criteria are below:

3.1 Inclusion Criteria:

1. Spinal cord injury at levels C3 to C5, and AIS A, B, or C
2. Greater than 3-months post injury or surgery to spinal column, arms, or shoulder
3. Ability to provide informed consent
4. Age 18 or over
5. Selected for participation based on investigator discretion

3.2 Exclusion Criteria:

1. Unable to follow instructions
2. Exhibit significant behavioral problems or impaired cognitive ability
3. Inability to provide consent
4. Non-English speaker

Clinicians involved in overseeing the device manipulation portion of the study will be expected to provide feedback about the APEX device.

4. Study Design

Part 1: The study design will be that of a single-arm pilot study with three to six human subjects (n=3-6). The study will inform the AMI design team of customer and APEX design requirements needed to develop an APEX device for commercial release. Participants will be expected to attend one 180 minute session. AbiliTech Medical personnel will be present for user training, during all device evaluation sessions and to troubleshoot technical problems. Courage Kenny Rehabilitation Institute (CKRI) personnel will collect subject medical history from medical records once consent and HIPAA authorization are obtained. Appendix 1, section 1 includes subject information to be collected. Potential participants will receive the consent form ahead of time to read and study. At the start of visit 1, subjects will be consented as a group and sign the HIPPA authorization. During device testing, Appendix 2 and 3 include assessment forms for device testing and questions subjects will be asked. Appendix 4, includes the device feedback survey which will be completed onsite before conclusion of the study. Subjects will use their personal internet connected mobile device to access and complete the survey. If subjects do not have a mobile device, a tablet will be available for subject to use and complete the survey. Audio recordings will be taken and videos of the mannequin will be recorded during device movement. Table 1 highlights activities to be performed in the User Focus Group.

Table 1: Visit 1: User Focus Group Activities

	Activity	Description
1: Consent (Up to 30 minutes)	1.1: Review and Sign Informed Consent Form (0-30 minutes)	Study participants will review and sign consent form in a group setting. They will be given time as to review and provide consent. Consent forms will be mailed to scheduled participants in advance of the focus group session.
2: Device Testing and Follow up (approximately 90 minutes)	2.1: Device Instructions and Operational Testing (60 minutes)	The clinician and AbiliTech Personnel will describe to the user on how to operate the device. The study participant will acclimate to use of the device. Data will be collected on the operation, function, and performance of the APEX device. Safety risks will be assessed.

	2.2: Device & Follow Up (10-15 minutes)	The study participant will provide feedback about their experience with the device.
3: Device Feedback (approximately 30-60 minutes)	3.1 Complete Survey	Subject performs Survey Monkey Survey on Device Preferences. Compensation provided upon survey completion.

Part 2 of the study will comprise of a clinician focus group to evaluate data gathered in the user focus group, AbiliTech bench testing, and motion capture data of the device function. Appendix 5 includes questions for clinicians to answer. Table 2 highlights the Clinician focus group activities.

Table 2: Visit 2: Clinician Focus Group Activities

	Activity	**Description**
1: Data Review (approximately 60 minutes)	1.1: Study Data Presentation	AbiliTech Medical will present data to CKRI clinical team. Data includes User focus group results and results device bench testing.
2: Device Feedback (approximately 60 minutes)	2.1 Discussion on Device	Clinicians and AbiliTech Medical team members will discuss the safety and clinical utility of the APEX device.

4.1 Test Schedule

Tests reflect common Activities of Daily Living, important safety measures, ancillary data, and subject satisfaction and interaction with the APEX Device crucial for successful development of the APEX Device.

Table 3: Test Schedule

Outcome Measure	**Notes**	**Visit**		
		After consent and HIPAA authorization obtained	1	2
Medical History	CKRI research staff will gather pertinent medical history of subjects ahead of clinical visit.	X		
Mannequin Test #1: Object Movement	Can the subject manipulate the device on a mannequin to manipulate an object in space? (Assistive Grip Device Allowed for use)? (Yes/No)		Assisted	
Mannequin Test #2: Object Movement	Can the subject manipulate the device on a mannequin to manipulate an object in a preferred pathway (Assistive Grip Device Allowed for use)? (Yes/No)		Assisted	

with Intention				
Mannequin Test #3: Button Push	Can the subject manipulate the device on a mannequin to push an elevator button? (Yes/No)		Assisted	
Mannequin Test #4: Lift Cell Phone	Can the subject manipulate the device on a mannequin to lift a cell phone? (Yes/No)		Assisted	
Safety: Observational Data on uncontrolled device guided movement	Observe if uncontrolled device movement occurs (Yes/No)		X	
Time using Device	Record time subject spends using device		X	
Open Ended Feedback	Data recorded from study participants from set questions. (See Appendix 2)		X	
Data Review				X
Clinician Feedback				X

4.2 Recruitment Plan

After IRB approval, subjects with upper extremity spinal cord injuries will be recruited through: 1) an internal search, match, and communication of subject records within Courage Kenny Rehabilitation Institution performed by an out-patient care coordinator and/or PI, 2) this trial will be posted and listed on www.clinicaltrials.gov with contact information available for possible enrollment of this study. Due to the size (n=3-6) of this study and recruitment methods, issues with recruitment of subjects is not anticipated. A list will be compiled and pre-screened by the principal investigator.

Potential study participants will be contacted by a research clinician to determine their interest in participating in the APEX pilot study. Consent forms will be sent out in advance of focus group session. The consent form will be reviewed with the potential study participants in a group setting.

5. Evaluations

5.1 Pre-study Evaluations

As part of the Screening, potential subject medical records will be evaluated by a clinician at Courage Kenny Rehabilitation Institute to match inclusion or exclusion criteria. No data will be collected or recorded until an informed consent form is reviewed and signed by the study participant. Patients who have indicated that they are not willing to provide access to their medical records for screening purposes (MRA 'No') will not be screened for study participation.

5.2 Evaluation During Study

During the visits, subjects will be assessed and supervised by the PI and/or the co-collaborators. Subjective and Objective tests and data will be collected for data analysis.

5.3 Post-Study Evaluations

None of the subjects will be followed or have data recorded after the visit, unless an adverse event is reported that relates to their participation in this study.

6. Outcomes

The fundamental purpose of conducting this pilot study is to examine the feasibility and safety of an APEX device, and examine the feasibility of an approach to ultimately be used in a larger scale study. Upon successful completion of the APEX Pilot Study, AbiliTech plans to submit for a Phase II NIH grant to complete product and clinical development on the path to commercial release of the APEX device.

The APEX Pilot Study includes assessments and other metrics that measure function and gather feedback as listed in Table 3.
Concept model device feasibility will be subjectively evaluated and defined as follows:

1. Manipulation of Mannequin: Were the users able to control the device with intention?
2. Usability Outcomes: User feedback on device performance, user input controls and overall comfort.
3. Clinician Feedback: Are there features that should be integrated into the device to enhance clinical utility?

Principal Investigator and Clinician feedback on overall device performance will be factored into the concept model feasibility results.

7. Criteria for Study Discontinuation

AbiliTech Medical will document any study participant subject discontinued from the APEX pilot study. The documentation will contain the rationale for study participant subject to be discontinued from the study. The PI must be notified immediately if a study participant subject discontinues the pilot study. Any data from the discontinued study participant subject will be maintained and may be used in the data analysis.

A study participant subject in this study may be discontinued for any of the following reasons:

- At the Investigator's discretion;
- At the subject's discretion;
- If the subject has a severe injury or illness within or outside of the study that affects their participation in the study;

8. Statistical Considerations

Data will be recorded and reported. No statistical analysis will be performed since the subject population is n=3-6. This study is designed to assess early feasibility and prepare for a larger clinical study in the future.

9. Retention of Records

In compliance with the ICH/GCP guidelines the investigator will maintain all CRFs and all source documents that support the data collected from each subject, and all trial documents as specified in Essential Documents for the Conduct of a Clinical Trial and as specified by the applicable regulatory requirement(s). The investigator will take measures to prevent accidental or premature destruction of these documents. Essential documents will be retained until at least two years after the last approval of a marketing application in an ICH region or at least two years have elapsed since the formal discontinuation of clinical development of the investigational product. These documents will be retained for a longer period if required by the applicable regulatory requirements or by an agreement with the sponsor. These documents will be retained for a longer period if required by Abbott Northwestern Hospital policies and procedures.

Original documents will be secured in a locked cabinet in the Courage Kenny Research Center. Copies that do not identify the study participant human subjects (using a code such as AMI-CKRI-XXX) may be shared with AbiliTech Medical for data and evaluation. AbiliTech will store the data in a locked cabinet on company premises with restricted access. Electronic copies with de-personalized data may be analyzed in an excel file. De-identified survey results will be collected and stored in Survey monkey web application for data analysis. Audio recordings will be transcribed and de-identified. Video recordings will be of device function and not of focus group participants.

10. Amendments to the Protocol

All protocol amendments will be submitted to the IRB. Amended protocol will be reviewed, approved and documented by the same method as the original protocol was reviewed and approved.
Once the amended protocol and all associated documents are reviewed and approved, the most recent protocol version and effective date will be changed on all pages of the protocol. Study personnel will notified of any protocol deviations.

11. Deviations from Investigative Plan

The Investigator is not allowed to deviate from the clinical investigation plan. Under emergency circumstances, deviations from the protocol to protect the rights, safety and well-being of human subjects may proceed without prior IRB. Such deviations shall be documented and reported to the IRB as soon as possible.

Deviations are will be reported in a site-specific deviation/violation log. Serious protocol violations will be reported in writing, with the corresponding log to the IRB within 24 hours.

12. Informed Consent Process

Potential study participants will be contacted by a research clinician to determine their interest in participating in the APEX pilot study. Consent forms will be sent out in advance of focus group session. The consent form will be reviewed with the potential study participants in a group setting.

The investigator and Research Staff will be responsible to assure that informed consent has been provided by a subject before study participation.

Prior to carrying out any protocol-specific procedures, investigators or designated staff will fully explain the details of the protocol, study procedures, and the aspects of subject privacy concerning research specific information. The original signed documents will become part of the subject's medical record, and each subject will receive a copy of the signed documents. All subjects must provide written informed consent prior to registration and treatment.

The following points will be observed during the informed consent process:

a) The principal investigator or her authorized designee conducts the informed consent process
b) All aspects of the clinical investigation that are relevant to the subject's decision to participate will be included
c) Any coercion or undue improper influence on, or inducement of, the subject to participate will be avoided
d) Ample time for the subject to read and understand the informed consent form and to consider participation in the clinical investigation will be used
e) Personally dated signatures of the subject and the principal investigator or an authorized designee responsible for conducting the informed consent process will be included in the informed consent form
f) The subject will be provided with a copy of the signed and dated informed consent form and any other written information
g) Important new information will be provided to new and existing subjects throughout the clinical investigation

Subjects that are unable to provide consent on their own will not be included in this study.

13. Reporting Requirements

The reporting plan for this study to relevant regulatory agencies will be as follows:

Progress Reports or Annual Reports

- Will be submitted at least once a year to reviewing IRB.

Study Completion or Termination

- Investigator will notify the reviewing IRB of the completion or termination of the study within 30 working days of termination and submit a final report within 6 months after completion or termination.

14. Risk to Participants

Participation in this trial is considered low risk. Subjects will only manipulate the device on a mannequin using a head worn accelerometer. The risks to the subjects are the normal risks that can occur with when using a remote control. To protect against *physical risk*, subjects will be closely monitored by CKRI clinical staff and AbiliTech Medical personnel during the entire time they are controlling the prosthesis.

15. References

1. National Spinal Cord Injury Statistical Center, Facts and Figures at a Glance. Birmingham, AL: University of Alabama at Birmingham, 2016, https://www.nscisc.uab.edu/Public/Facts%202016.pdf .

2. National Spinal Cord Injury Statistical Center, University of Alabama at Birmingham, 2015 Annual Statistical Report – Complete Public Version https://www.nscisc.uab.edu/ .

3. Anderson, Kim D., "Targeting Recovery: Priorities of the Spinal Cord-Injured Population", JOURNAL OF NEUROTRAUMA, Volume 21, Number 10, 2004, Pp. 1371-1383.

4. Snoek, G. J., IJzerman M. J., Hermens, H. J., Maxwell, D., Biering-Sorensen, F., "Survey of the needs of subjects with spinal cord injury: Impact and priority for improvement of hand function in tetraplegics.", Spinal Cord. (2004):42, 526-532.

5. "Spinal Cord Injury: Hope Through Research", NINDS, NIH Publication No. 13-160, July 2013, https://www.ninds.nih.gov/Disorders/Subject-Caregiver-Education/Hope-Through-Research/Spinal-Cord-Injury-Hope-Through-Research

6. Harness ET, Yozbatiran N, Cramer SC, "Effects of intense exercise in chronic spinal cord injury.", Spinal Cord, 2008 .Nov; 46(11):733-7.

7. Dunn JA, Sinnott KA, Rothwell AG, Mohammed KD, Simcock JW, "Tendon Transfer Surgery for People With Tetraplegia: An Overview.", Arch Phys Med Rehabil, 2016 Jun;97(6 Suppl):S75-80.

8. Fox IK, Davidge KM, Novak CB, Kahn LC, Juknis N, Ruvinskaya R, Mackinnon SE., "Nerve Transfers to Restore Upper Extremity Function in Cervical Spinal Cord Injury: Update and Preliminary Outcomes.", Plast Reconstr Surg., 2015 Oct; 136(4):780-92.

9. Patil S, Raza WA, Jamil F, Caley R, O'Connor RJ., "Functional electrical stimulation for the upper limb in tetraplegic spinal cord injury: a systematic review.", J Med Eng Technol. 2014;39(7):419-23.

10. Bickel CS, Yarar-Fisher C, Mahoney ET, McCully KK., "Neuromuscular Electrical Stimulation-Induced Resistance Training After SCI: A Review of the Dudley Protocol.", Top Spinal Cord Inj Rehabil. 2015 Fall;21(4):294-302.

11. Beekhuizen, K. S. & Field-Fote, E. C., "Massed practice versus massed practice with stimulation: Effects on upper extremity function and cortical plasticity in individuals with incomplete cervical spinal cord injury.", Neurorehabilitation and Neural Repair, (2005);19, 33-15.

12. Atkins MS, Baumgarten JM, Yasuda YL, Adkins R, Waters RL, Leung P, Requejo P., "Mobile arm supports: evidence-based benefits and criteria for use.", J Spinal Cord Med. 2008;31(4):388-93.

13. Zariffa J, Kapadia N, Kramer JL, Taylor P, Alizadeh-Meghrazi M, Zivanovic V, Alibisser U, Willms R, Townson A, Curt A, Popovic MR, Steeves JD., "Relationship between clinical assessments of function and measurements from an upper-limb robotic rehabilitation device in cervical spinal cord injury.", IEEE Trans Neural Syst Rehabil Eng. 2012 May;20(3):341-50.

14. Peters HT, Page SJ, Parsch A., “Giving Them a Hand: Wearing a Myoelectric Elbow-Wrist-Hand Orthosis Reduces Upper Extremity Impairment in Chronic Stroke.”, Arch Phys Med Rehabil. 2017 Jan 24. Pil: S0003-9993(17)30026-6.

15. McColl MA, Paterson M, Davies D, Doubt L, Law M., “Validity and community utility of the Canadian Occupational Performance Measure.”, Can J Occup Ther. 2000 Feb;67(1):22-30.

16. Hicks AL, Martin Ginis KA, Pelletier CA, Ditor DS, Foulon B, Wolfe DL., “The effects of exercise training on physical capacity, strength, body composition and functional performance among adults with spinal cord injury: a systematic review.”, Spinal Cord (2011) 49, 1103-1127.

17. Baker C, Wong D, “Q.U.E.S.T.: A process of pain assessment in children”, Orthopaedic Nursing, 6(1):11-21, 1987.

18. Gates, D. H., Walters, L. S., Cowley, J., Wilken, J. M., & Resnik, L., “Brief Report−Range of motion requirements for upper-limb activities of daily living.”, American Journal of Occupational Therapy, (2016) 70, 7001350010. http://dx.doi.org/ 10.5014/ajot.2016.015487

Appendix 1: Medical History Report Form

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612-483-6100 www.abilitechmedical.com

AbiliTech Medical APEX Study
Medical History Report Form

Subject Information

Subject ID Number _____ Year of birth _____ Height (in) _____ Weight (lbs) _____

Diagnosis: _____ Level of Injury: _____ AIS Score: _____

MMT Scores: Shoulder Flexion _____ Adduction _____ Elbow Flexion _____ Elbow extension _____

Forearm Pronation_____ Forearm Supination _____

Hand dominance: ☐ Left ☐ Right **Gender:** ☐ Male ☐ Female

Subject Meets Inclusion/Exclusion Criteria: ☐ Yes ☐ No **Year of Injury:** _____

Subject Participating in another clinical trial: ☐ Yes ☐ No _____(if yes, please list trial)

Wheelchair mfr/model _____ /_____ **Independent mobility/balance** *(please check category that best describes subject ability)* ☐ Ambulatory ☐ Supine to sit ☐ Sit to stand

Notes

Appendix 2: Pilot Usability Testing Form

5209 Morgan Ave. S. Minneapolis, MN 55419
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AbiliTech Medical APEX Study
Pilot Usability Testing Form

Subject Information

Subject ID Number _____

Subject Assessment with APEX

Is the subject familiar with smartphone applications? ☐ Yes ☐ No

Can the subject use voice control features of the application to toggle between device modes? ☐ Yes ☐ No

Can the subject use the head worn accelerometer to control the APEX device movement? ☐ Yes ☐ No

Can subject power the device on/off? ☐ Yes ☐ No

Can the subject move the APEX on a mannequin in the following Ranges of Motion?

Shoulder
Flexion Powered ROM: 0 to 60° ☐ Yes ☐ No

Shoulder Abduction Powered ROM: 0 to 30° ☐ Yes ☐ No

Horizontal Internal Rotation Powered ROM: 35 to -35° ☐ Yes ☐ No

Compound Shoulder ROM (Flexion, internal rotation, horizontal adduction: limited in horizontal plane): 0 to 100° ☐ Yes ☐ No

Elbow
Elbow Flexion/Extension Powered ROM: 0 to 130° ☐ Yes ☐ No

Forearm
Supination Powered ROM: 0 to 60° ☐ Yes ☐ No

Pronation Powered ROM: 0 to 50° ☐ Yes ☐ No

Can the subject move the APEX on a mannequin to complete the following tasks?

Control APEX device to manipulate objects in space ☐ Yes ☐ No

Control APEX to move an object in a preferred pathway ☐ Yes ☐ No

Control APEX device to push buttons ☐ Yes ☐ No

Control APEX to lift a water bottle from table level ☐ Yes ☐ No

Control APEX to lift a phone ☐ Yes ☐ No

Uncontrolled device movement observed: ☐ **Yes** ☐ **No** *(if yes, please comment below)*

Time spent using the device: _____(min)

Notes

Utility

1. On a scale of 1 to 5, how would the APEX System improve your ability to use your arms? (1 no improvement - 5 strong improvement)

2. In general, what would you like to be able to do with your arms?

3. What are three to five Activities of daily living that you wish you could perform, listed in priority?

4. Do you think using the APEX device you could do [each of the ADL they stated]?

Device Feedback

1. What is your general impression of the APEX System, knowing the development phase it is in?

2. Would you use the APEX System? How much? Where? When? For what Uses?

3. What do you like about the APEX System?

4. What do you dislike about the APEX device?

5. What could be improved about the APEX device?

6. What is your opinion about the size, appearance, texture, color, and/or noise of the APEX device?

7. What is your opinion on the control system?

8. What type of control system would you prefer?

9. What is your opinion on the user interface?

10. What improvements in the control system or user interface would you like?

11. Would you be interested in predefined pathways of motion to assist in control of the device?

12. What safety concerns do you have about the APEX system?

13. What could be done to minimize these risks?

Appendix 4: AbiliTech Medical APEX Device Feedback Questions

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AbiliTech Medical APEX Device
Subject Device Survey Questions

APEX Survey Monkey Questions

1. What is your gender?

2. What is your age?

- 18-29 years old
- 30-49 years old
- 50-64 years old
- 65 years and over

3. How long ago was your injury?

- less than 6 months
- 6 months to 1 year ago
- 1 - 2 years ago
- 2 - 5 years ago
- 5- 10 years ago
- 10-20 years ago
- 25+ years ago

4. How were you injured?

- Sports (any type including diving, surfing, ...)
- Transporting (car, truck, ATV, motorcycle, bike, ...)
- Slip, Trip, or Fall (including falls from height)
- Assault (stab, gunshot, ...)
- Other (please specify)
- Non-Traumatic Cause (birth, infected, tumor, ...)
- Other Traumatic Cause
- Unknown

5. My injury is defined as:

- ASIA A: No Motor & Sensory
- ASIA B: No Motor & Some Sensory
- ASIA C: Significant Motor & Some Sensory
- ASIA D & E: Functional Motor Skills Below Injury
- Unsure

6. What level is your injury?

- ○ C1
- ○ C2
- ○ C3
- ○ C4
- ○ C5
- ○ C6
- ○ C7
- ○ C8
- ○ Other (please specify)

7. I have full functional strength in my arms

0 (Limited Strength) — 100 (Full Functional Strength)

8. I have fully functional hand grip

0 (Limited) — 100 (Full Functional)

9. Assuming your limited function, please list the top three things you would want to do with a shoulder, elbow, hand movement device.

10. I use a...

- ☐ Power Wheelchair
- ☐ Manual Wheelchair
- ☐ Cane/ Walker
- ☐ No Assistance Required
- ☐ Please list Device Manufacturer:

11. If you are unable to do so, how Important is the ability to independently...

	Very Important	Important	Neutral/ Undecided	Unimportant	Very Unimportant	N/A, Functional
Actively move your arm(s)? (Shoulder & Elbow)	☐	☐	☐	☐	☐	☐
Open your hand?	☐	☐	☐	☐	☐	☐
Close your hand?	☐	☐	☐	☐	☐	☐
Twist your palm? (Pronate and Supinate)	☐	☐	☐	☐	☐	☐
Move your wrist?	☐	☐	☐	☐	☐	☐
Improve pinch or grasp strength in your hand?	☐	☐	☐	☐	☐	☐
Pick up everyday objects? (Pen, fork, food, soda can, folder/ notebook)	☐	☐	☐	☐	☐	☐
Perform Activities of Daily Living? (Brushing teeth, eating, drinking, grooming, ...)	☐	☐	☐	☐	☐	☐

Other (please specify)

12. Which statement best describes your current living arrangement?

- ◯ I live independently
- ◯ I live with my family
- ◯ I live in a post-acute care facility
- ◯ I live in a long term care facility
- ◯ Other (please specify)

13. What are the top five things you would like the device to help you accomplish that you can not do?

	1st	2nd	3rd	4th	5th	N/A
Grooming	○	○	○	○	○	○
Dressing	○	○	○	○	○	○
Self-catherize	○	○	○	○	○	○
Perform my own bowel program	○	○	○	○	○	○
Wheeling	○	○	○	○	○	○
Transferring	○	○	○	○	○	○
Cleaning	○	○	○	○	○	○
Food preparation	○	○	○	○	○	○
Desk/Computer Work	○	○	○	○	○	○
Eating and Drinking Independently	○	○	○	○	○	○
Scratch an itch	○	○	○	○	○	○
Shake hands	○	○	○	○	○	○
Wave	○	○	○	○	○	○
Hug a loved one	○	○	○	○	○	○
Cell Phone	○	○	○	○	○	○
Driving	○	○	○	○	○	○
Manage my power chair independently	○	○	○	○	○	○

Other (please specify)

14. For which activities of daily living are currently receiving help from a caregiver? (Check all that apply)

- [ ] Grooming
- [ ] Dressing
- [ ] Self-catheterize
- [ ] Performing my bowel program
- [ ] Wheeling
- [ ] Transferring
- [ ] Cleaning
- [ ] Food preparation
- [ ] Desk/Computer Work
- [ ] Eating and Drinking Independently
- [ ] Scratch an itch
- [ ] Shake hands
- [ ] Wave
- [ ] Hug a loved one
- [ ] Cell Phone
- [ ] Driving
- [ ] Manage my power chair independently
- [ ] Other (please specify)

15. What forms of transportation do you use? (Check all that apply)

- [ ] I own an accessible car/van
- [ ] I rely upon a caregiver for transportation
- [ ] I use metro mobility or similar transportation
- [ ] Public Transit
- [ ] Taxi
- [ ] Other (please specify)

16. I have seen the following specialists within the last (blank) years:

	1 year	3 years	5 years	Over 5 years	N/A
General Practice Physician	○	○	○	○	○
Physical Medical Rehabilitation Physician	○	○	○	○	○
Neurologist	○	○	○	○	○
Occupational Therapist	○	○	○	○	○
Physical Therapist	○	○	○	○	○
Respiratory Therapist	○	○	○	○	○
Orthotist/Wheelchair Fitting Expert	○	○	○	○	○
Orthopedic Pain Management Specialist	○	○	○	○	○
Cardiologist	○	○	○	○	○
Urologist	○	○	○	○	○

Other (please specify)

17. My SCI doctor is at (blank hospital):

18. How many times do you visit a doctor or medical professionals in a one year period?

19. I experience pain:

- ☐ Daily
- ☐ Weekly
- ☐ Monthly
- ☐ I do not experience pain
- ☐ Other (please specify)

20. Rate your average pain. (0 is none, 10 is worst possible pain)

0 10

21. Where is your pain located?

22. I have spasticity:

23. I take medicine for spasticity:

24. I have shoulder subluxation:

25. Do you practice in-home therapy or fitness?

If yes, how often?

26. Do you participate in therapy outside of the home?

If yes, how often?

27. What type of insurance do you have? (Check all that apply)

- Private
- Medicaid
- Employer
- Disability
- None

28. Do you currently pay for a caregiver?

- ◯ Yes, Private Pay
- ◯ Yes, Insurance/ Government Assistance
- ◯ No

29. What kind of home care do you have? (Check all that apply)

- ☐ Nurse
- ☐ Personal Care Assistant
- ☐ House Keeper/ Cleaner
- ☐ None
- ☐ Other (please specify)

30. How much do you pay your care giver per hour?

31. How many hours per day do you require a paid caregiver?

How many hours are you approved for?

32. Does a family member provide care?

If yes, how many hours per day of care is done by a family member?

33. Do you track your yearly healthcare costs?

If yes, what is your annual cost?

34. Does your injury impact any family members ability to work?

- ◯ Yes
- ◯ No

35. Does your arm/hand function impact your ability to work in your field of choice?

- ◯ Yes
- ◯ No
- ◯ Other (please specify)

36. Are you currently employed?

- ◯ Yes
- ◯ No

37. Would you work if you could use your arms/hands?

- ◯ Yes, Part Time
- ◯ Yes, Full time
- ◯ No
- ◯ Other (please specify)

38. Would you go to school if you could use your arms/hands?

- ◯ Yes, Part Time
- ◯ Yes, Full time
- ◯ No
- ◯ Other (please specify)

39. Please select and rank your satisfaction on a scale of 1 (low) - 10 (high) with the assistive devices you have used for upper limb impairment treatment

	1	2	3	4	5	6	7	8	9	10	N/A Never Used
Basic Splint	○	○	○	○	○	○	○	○	○	○	○
Tenodesis Splint	○	○	○	○	○	○	○	○	○	○	○
Bioness	○	○	○	○	○	○	○	○	○	○	○
Myopro	○	○	○	○	○	○	○	○	○	○	○
Hocoma/Armeo Spring	○	○	○	○	○	○	○	○	○	○	○

Other (please specify)

40. Do you use any assistive devices for arm/hand function? What do you like about them?

41. What limitations have you found with other assistive devices for arm/hand function?

42. Please react to the following statements on assistive device features.

	Yes	Maybe	No	N/A
If I could use my arms, I'd be willing to use accessories to compensate for a loss of hand function	○	○	○	○
A three finger grip would meet my requirements	○	○	○	○
A five finger grip would meet my requirements	○	○	○	○
I would be interested in seeing a weekly progress report of my activity with my arms, similar to a fitbit	○	○	○	○
A device would need to show my daily or weekly activity progress on a smartphone	○	○	○	○

43. Would you be interested in...

	Yes	Maybe	No
Using an app to see with your phone to see how much you have used your exoskeleton?	○	○	○
Using an app that shows you how you have built strength or function?	○	○	○
Using an app that connected with your clinician to show them your usage and progress with the device?	○	○	○
Using an app to see daily reports?	○	○	○
Using an app to see weekly reports?	○	○	○
Using an app to see monthly reports?	○	○	○

44. To control an upper limb prosthosis I would like to use:

	Very Interested	Interested	Maybe	Uninteresed	Very Uninteresed
Button/ Switch	○	○	○	○	○
Body/ Head Activated Movement	○	○	○	○	○
Voice Control	○	○	○	○	○
Eye Tracking	○	○	○	○	○
Mouth Bite Click	○	○	○	○	○
Sip n Puff	○	○	○	○	○
EMG (Trace but detectable muscle movement)	○	○	○	○	○
Pressure Sensors	○	○	○	○	○

Other (please specify)

45. How important is:

	Very Important	Important	Neutral	Unimportant	Very Unimportant	N/A
Wrist Support	○	○	○	○	○	○
Wrist assisted movement with finger assisted movement	○	○	○	○	○	○
Stabilize the wrist during hand and finger motion	○	○	○	○	○	○
Individual finger movement (i.e.: just move index or middle finger at a time)	○	○	○	○	○	○
Lightweight (under 2 lbs)	○	○	○	○	○	○
Mid weight (2-4 lbs)	○	○	○	○	○	○
4-6lbs	○	○	○	○	○	○
Fashionable/ Style	○	○	○	○	○	○
Durability	○	○	○	○	○	○

Other (please specify)

46. What other interventions have you done to work on improving your hand/arm function?

47. It is important to me to have use of both of my arms:

- ○ Yes, I need assistance for both arms
- ○ No, I need assistance for a single arm
- ○ Other (please specify)

48. Is there a caregiver available to assist with putting on a hand based device?

- ○ Yes
- ○ No

49. If you play video or computer games, my top three favorites are:

50. Which of the following is most important to me about how the device looks? (Check all that apply)

- [ ] Color
- [ ] Shape
- [ ] Size
- [ ] Texture

51. I would use this device for X hours a day

- ◯ 1-2 hours
- ◯ 2-4 hours
- ◯ 4-6 hours
- ◯ 6+ hours

52. If this device were useful to me and insurance would not cover it, the maximum amount I would pay for a hand grip device would be...

- ◯ $1,000
- ◯ $2,500
- ◯ $5,000
- ◯ $10,000
- ◯ I would not pay for this

53. How long should the battery last until it needs to be recharged?

- ◯ 4 hours
- ◯ 8 hours
- ◯ 24 hours
- ◯ 48 hours

54. Other than lack of voluntary movement, do you have any limitations that would prevent finger or hand movement?

55. Do you have any safety concerns for this device?

56. If safety concerns, please comment.

Appendix 5: AbiliTech Medical APEX Device Clinician Feedback Questions

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AbiliTech Medical APEX Device
Clinician Feedback Questions

APEX Study Questions

1. Are there features that should be integrated into the device to enhance clinical utility?

2. Do you have any safety concerns for the use of this device?

3. Do you have feedback on how safety mechanisms can be improved?

4. How would this device benefit your patients?

5. What motions or activities of daily living would be most meaningful for your patients?

6. What type and intensity of training and acclimation would you like to work with your patients for this device?

7. Are you interested in monitoring subject compliance with device?

8. What improvements of the device would you suggest?