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14. ABSTRACT Our military forces are experiencing an increase in injury to the upper extremity from combat and strains of overuse resulting in pathologies such as tendonitis, bursitis, and impingement. Rehabilitation using robotics offers significant advantages over manual therapy such as accuracy and consistency of applied forces, quantitative measures of performance, and lack of therapist fatigue. This project will implement common shoulder therapy protocols on a robotic arm exoskeleton and conduct a pilot study to evaluate operational use. The goals of this project are to: 1) transfer common shoulder therapy protocols to the exoskeleton; 2) design, code, and test the exoskeleton control system; 3) conduct a pilot study to validate operation on a range of subjects. Protocols will be developed based on biomechanical analyses of tasks being performed using conventional shoulder therapy protocols. Control algorithms will be used to produce resistance therapy about the shoulder axes as well as generate functional movement patterns of the arm. The distributed software design will incorporate a NASA fail-safe architecture that continually monitors potentially hazardous conditions to ensure patient safety. Through the focused development effort proposed here, the Maryland-Georgetown-Army (MGA) Exoskeleton has the potential to become a highly effective tool in treatment facilities ranging from military rehabilitation centers to sports therapy clinics.					
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2 Introduction

Rehabilitation using robotics offers significant advantages over manual therapy or passive exercise machines such as the application of consistent and accurate forces, quantitative measures of performance, and programmable resistance profiles. An exoskeleton, which surrounds the whole arm or leg, offers additional advantages because forces can be applied at different points along the limb to target specific joints or muscle groups.

The goal of this project was to implement shoulder therapy protocols on the MGA Exoskeleton and conduct a limited pilot study to evaluate operational use. Protocols were developed based on biomechanical analyses of tasks being performed using conventional shoulder therapy protocols. Control algorithms were used to produce resistance therapy about the shoulder axes as well as generate functional movement patterns of the arm. The distributed software design incorporated a NASA fail-safe architecture that continually monitors potentially hazardous conditions to ensure patient safety.

The project was led by the *Imaging Sciences and Information Systems (ISIS) Center* of the Department of Radiology at Georgetown University. Our project collaborators were the *Space Systems Laboratory (SSL)* in the Department of Aerospace Engineering at the University of Maryland and the *Center for Applied Biomechanics and Rehabilitation Research (CABRR)* at the National Rehabilitation Hospital/Catholic University of America. The SSL built the exoskeleton and provided hardware and software support, and CABRR provided support for protocol development and clinical testing. The funds provided under this grant were leveraged with prior development from other synergistic activities to further advance this effort.

3 Report Body

This is the final report for Cooperative Agreement # W81XWH-08-2-0010 covering the period from January 15, 2008 to September 30, 2009. A no-cost extension was granted for the period of January 15, 2009 to September 30, 2009. A brief overview is given and the research associated with each of the tasks in the statement of work is then described. The reader will be referred to specific documents in the appendix for more details.

The research over the initial year was targeted at building the repertory of tools necessary to support rehabilitation protocols on the exoskeleton. These include developments in the areas of composite control, exercise protocols, graphical interfaces, and safety monitoring. Several new controllers were coded and tested successfully. All of the isolateral shoulder exercises and two functional training protocols were developed and tested. The encoder position checks and current monitor checks were then developed for integration into the safety system. The clinical graphical user interfaces for selecting exercise parameters were developed and integrated with the control system. The human subjects test protocol and consent form were submitted and approved by both the MedStar IRB and U.S. Army HRPO in September, 2008.

One important task that was not in the original statement of work was the development of a new upper arm cuff attachment for the exoskeleton. The cuff was relocated from the elbow to the upper arm to provide a more ergonomic interface and cause less interference with elbow movement. A leg cuff attachment from a Lokomat™ Orthosis was adopted for use as an upper arm attachment (see Fig. 1). However, the upper arm links were too thin and flexible to support the force sensor attached between the link and arm cuff, so a new set of upper arm links were designed and built (see Fig. 2). The original mechanical designer for the exoskeleton was hired as an independent contractor to complete this effort.



Figure 1: Old upper arm attachment used an elbow brace (left), whereas the new system uses an upper arm brace (right). The JR3 force sensor (blue disc), connects the arm brace to the links.

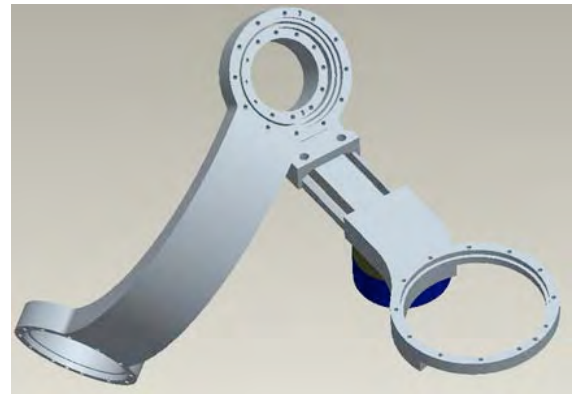


Figure 2: CAD drawings of old (left) and new (right) upper arm linkages. The thickness was increased from 1/4 inch to 3/4 inch to decreasing flexing at the force-torque sensor mount.

3.1 Task 1: Exoskeleton Modeling and Shoulder Biomechanics

This task focused on the development of a dynamic model of the exoskeleton to be used for control feedforward and on the implementation of a biomechanical model of shoulder elevation that for driving the scapula joint.

3.1.1 Develop exoskeleton dynamic model

The dynamic model consisted of two parts: mass model (for gravity compensation), and a friction feedforward model. These are broken down below.

- a) Gravity Modeling: A program was written in Mathematica to estimate the gravitational load based on the mass model parameters from the CAD model. The estimated link mass parameters as a function of the passive adjustable link length segments for the scapula, upper arm, forearm (L_S , L_U , L_F) are shown in Table 1.

Table 1: Estimated link mass parameters from the Mathematica program.

Link	m (kg)	pcm (m)
1	3.54	0.148801 - 0.76083 Ls -0.111184 - 0.439266 Ls 0.10898
2	2.33	0. 0.049 0.172
3	3.64	0. -0.121 0.122
4	1.598	-0.000635795 0.0852407 - 0.561968 Ls 0.115307 - 0.852245 Ls
5	1.95	-0.0006 -0.0356 - 0.4 Lf 0.0658

The Mathematic program was ported over to C code and tested on the exoskeleton. Preliminary results are promising, and the mass estimates were refined for the new upper arm and scapula links.

- b) Friction Modeling: The exoskeleton was disassembled so that the friction of each joint could be characterized for model feedforward in the control system. The results of the friction testing are summarized in Fig. 3. Each joint shows a characteristic stiction effect near zero velocity and a linear viscous effect at higher speeds. This model was ported over to C code and tested on the exoskeleton. The model seems to overcompensate, but works fairly well when reduced to 80%.

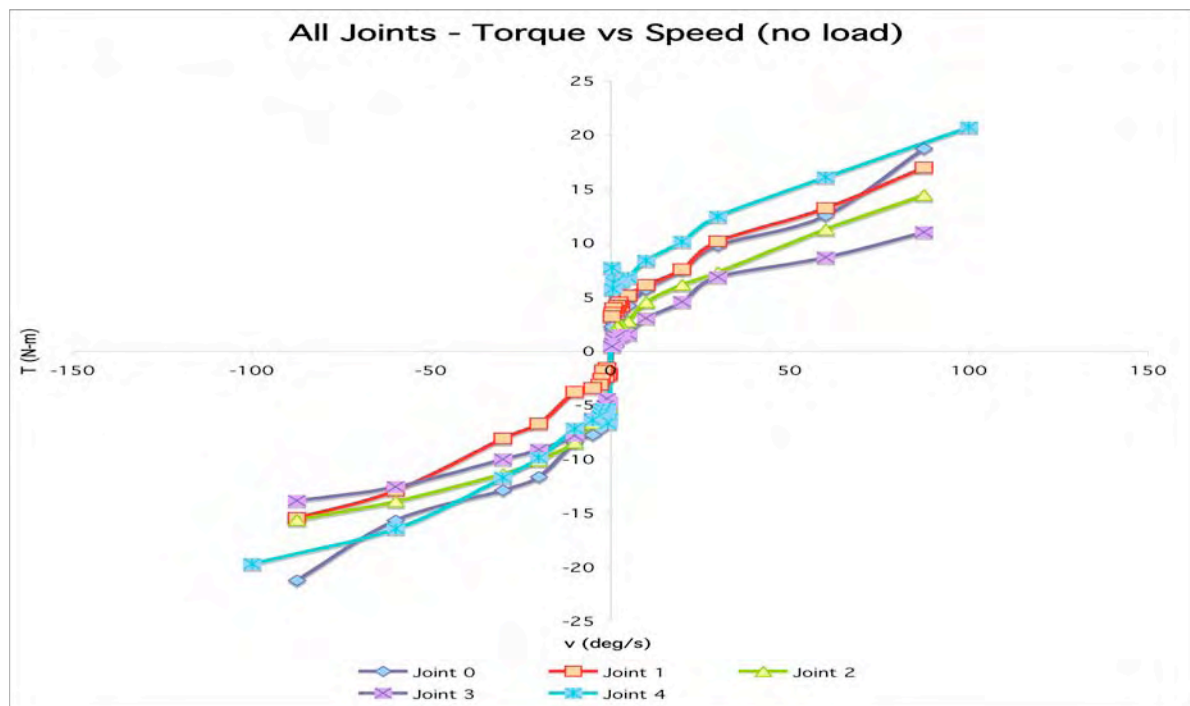


Figure 3: Friction torque versus speed of the five powered exoskeleton joints.

3.1.2 Develop biomechanical model of scapula motion

The biomechanical model of shoulder elevation shown in Fig. 4 (Moeslund et al, 2003) was used to drive the scapula joint to keep the exoskeleton shoulder aligned with the human shoulder. The humerus angle was calculated from the exoskeleton joint angles and used to determine the humerus elevation. The humerus elevation was then input into this model to determine the desired shoulder elevation, which was then divided by the scapula link length to determine the desired rotation angle of the scapula joint. A PD controller was then used to drive the scapula joint to keep the exoskeleton shoulder aligned with the subject's shoulder. Details can be found in Carignan et al, 2008 (Appendix 8.2).

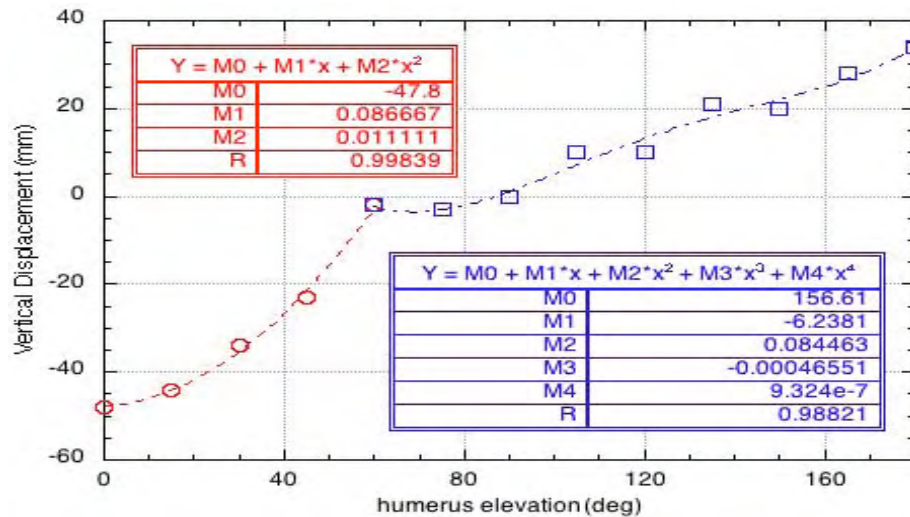


Figure 4: Vertical displacement of shoulder joint as function of humerus elevation.

3.2 Task 2. Develop exoskeleton rehabilitation exercises and controllers

This task entails the development of the shoulder exercises and associated controller to drive them in different modes.

3.2.1 Select shoulder therapy exercises

The exercise tasks generated in this study are shown in Table 2 along with arm position and load parameters. The position of the upper arm is represented in global coordinates as illustrated in Fig. 5 (left) with the shoulder at the center of the globe (Doorenbosch et al, 2003). Longitude represents planes of elevation where the south pole is 0° (arm straight down) and the equator is at 90° (arm horizontal). Latitudes represent the amount of elevation in a plane of elevation. An azimuth of 0° represents the arm pointing straight out to the right side in the equatorial plane as shown on the right in Fig. 5, and 90° indicates the arm pointing straight ahead. The orientation of the forearm relative to this latitude is the angle of the upper arm. The body planes are shown in Fig. 6. Most of the hand movement during these tasks occurs in one or more of these planes with the exception of the scapula plane oriented at 30° with respect to the coronal (a.k.a. frontal) plane. Some of the configurations of the exoskeleton for the isolateral shoulder exercises are shown in Fig. 7.

Table 2: Exercise tasks for pilot study protocol at NRH.

Tasks	Upper Arm Position		Movement Plane	Load/Resistance*
	Latitude	Longitude		
Isolateral Exercise				% 1RM
Arm Extension	0°/90°	90°	Sagittal	25-50-75
Lateral Raise	0°/90°	30°	Scapula	25-50-75
Internal/External Rotation	0°	30°/150°	Transverse	25-50-75
Rear Deltoid	90°	90°/0°	Tranverse	25-50-75
Functional Training				N
Reach to Pop Balloons	90°/120°	30°/150°	Various	10
Paint Wall with Roller Brush	60°	+60°/-60°	Coronal	20/40

*% of 1 rep max or hand force

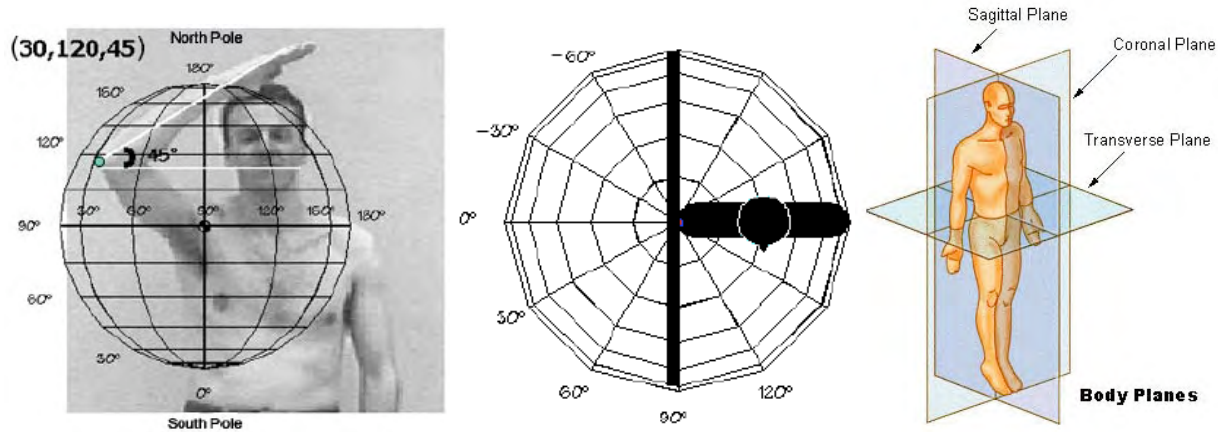


Fig. 5: Global coordinate system used to represent arm configuration: Fig. 6: Body planes. front view (left), and equatorial plane (right).

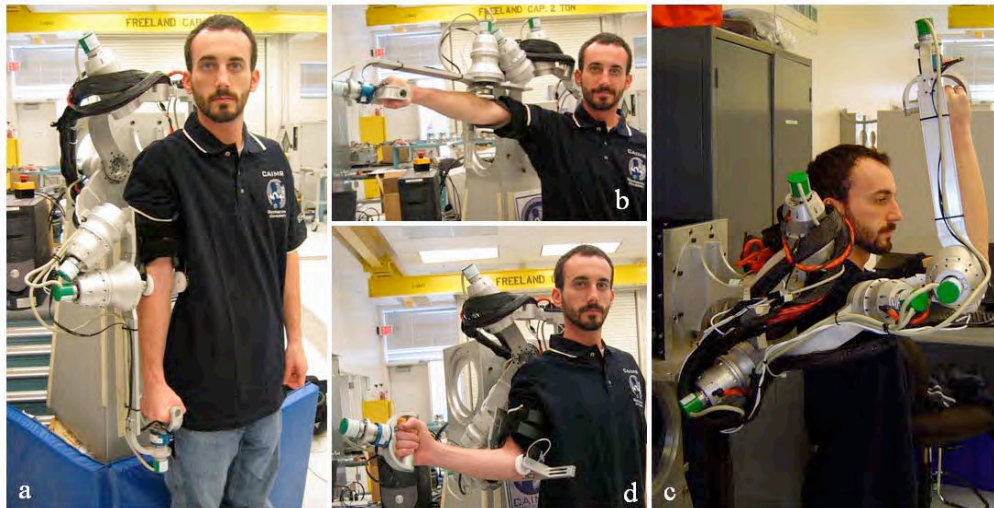


Figure 7: MGA Exoskeleton in several configuration: (a) full shoulder adduction, (b) 90° shoulder abduction, (c) mid-elbow flexion, and (d) full lateral (external) rotation.

The graphical interface developed for the virtual wall-painting task was developed using the open source Qt4 graphics application and is shown in Fig. 8. The virtual wall is located in the Coronal plane at about 40 cm from the intersection of the body plane axes. The subject starts with their hand a few centimeters in front of the wall and then moves forward until "contact" is

made with the wall as seen in Fig. 9. The subject is told to hold a constant force on the surface while painting the wall with the virtual roller brush.

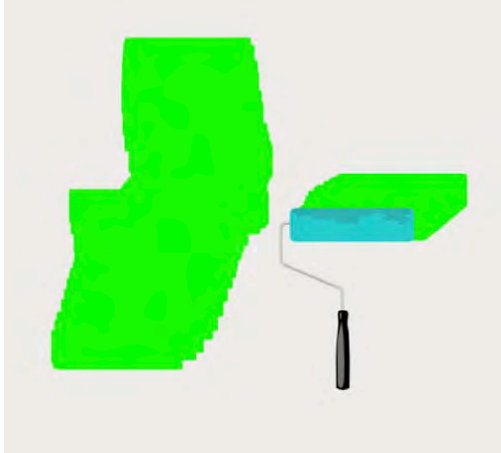


Fig. 8: Qt graphics display developed for virtual wall painting task.

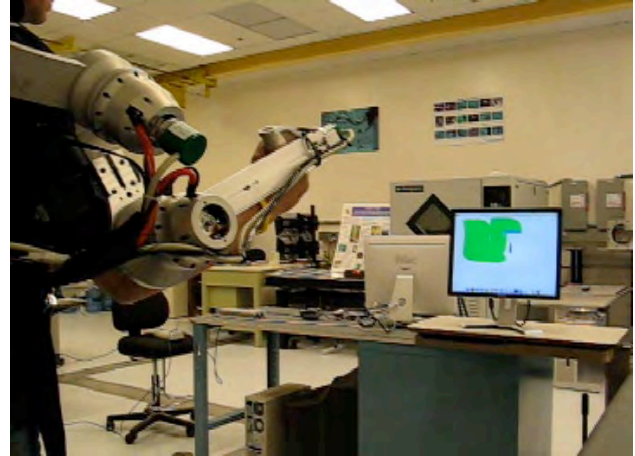


Fig. 9: Exoskeleton handle exerts forces back on subject as roller brush contacts wall.

3.2.2 Develop controllers to support the protocols

The composite controller architecture shown in Fig. 10 was developed to control the exoskeleton. This allows the simultaneous control of different sets of joints at the same time (Carignan et al, 2007). The exoskeleton joints are first parsed into mutually exclusive sets of subcontrollers based on the activation of human arm joints during the exercise: scapula (Sc), shoulder (GH), elbow orbit (EO), elbow pitch (EP), and wrist translation (XW). Only certain combinations are allowed; for example, shoulder GH/elbow pitch or wrist translation/elbow orbit are permitted, but not wrist translation/shoulder GH because they have overlapping joints. Each of these joint sets can be selected to operate in either impedance or admittance mode depending upon the desired impedance values. The joint servo modes are set by the composite controller to accept either position or torque commands from the corresponding subcontroller, such as the ones used for the wall-painting task shown in Fig. 11.

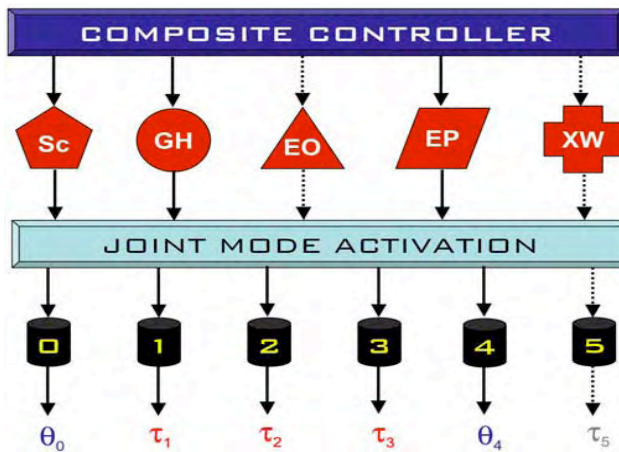


Fig. 10: Composite controller activates sets of modules which then activate joints.

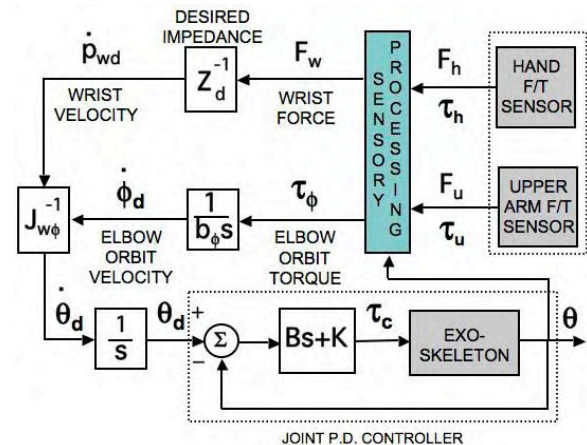


Fig. 11: Admittance (XW) and elbow orbit (EO) control modules used for wall-painting.

3.3 Task 3. Conduct pilot study with the exoskeleton

This task is centered around developing the test protocol and clinical interfaces for controlling and monitoring the exoskeleton during the clinical trials.

3.3.1 Develop test protocol and clinical interfaces

The MedStar IRB approval and human subject protocol for validation testing of the exoskeleton at the National Rehabilitation Hospital are shown in Appendices 8.11 and 8.12, respectively. The protocol was submitted to the MedStar Institute Review Board and USAMRMC Office of Human Subject Protections and approved in September, 2008.

Several clinical graphical user interfaces were developed to control and monitor the exoskeleton for testing. The isolateral exercise control panel shown in Fig. 12 allows the therapist to select the axis of rotation (left) and choose either isotonic or isokinetic modes (right). The level or resistance or speed can be adjusted using a radio button that sets discrete values or a slider for continuous adjustment.

The prototype version of the telemetry panel is shown in Fig. 13. This GUI will allow the clinician to view the position of the exoskeleton in different planes as well as the forces in the elbow (upper arm) and hand force sensors. An advanced version will eventually incorporate a 3D graphical view of the exoskeleton and ellipsoids to represent force levels. Safety status will also be displayed on this panel.

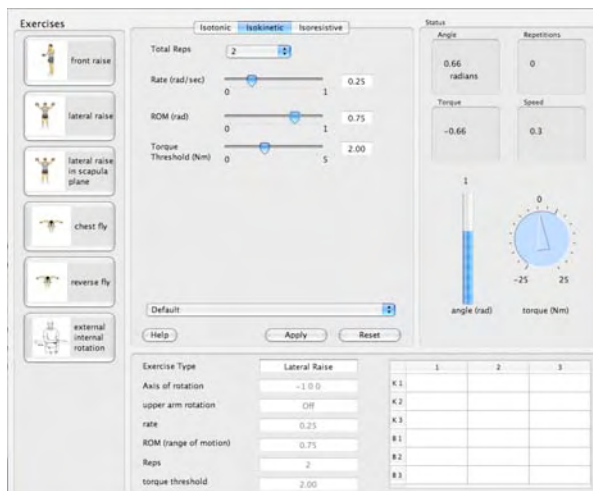


Fig. 12: Clinician control panel developed for isolateral shoulder exercises.

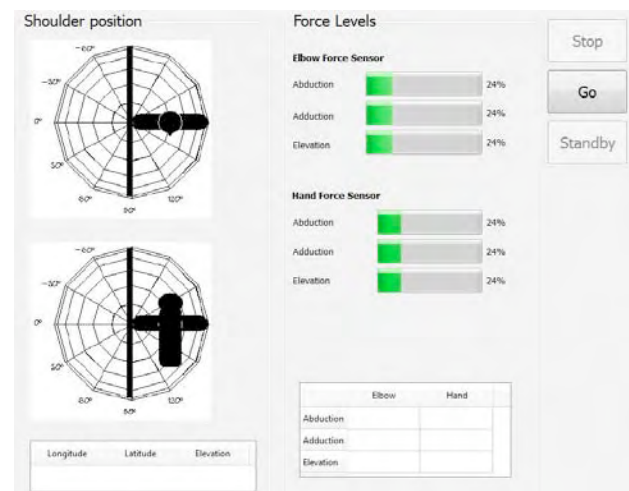


Fig. 13: Telemetry panel prototype for monitoring position and force.

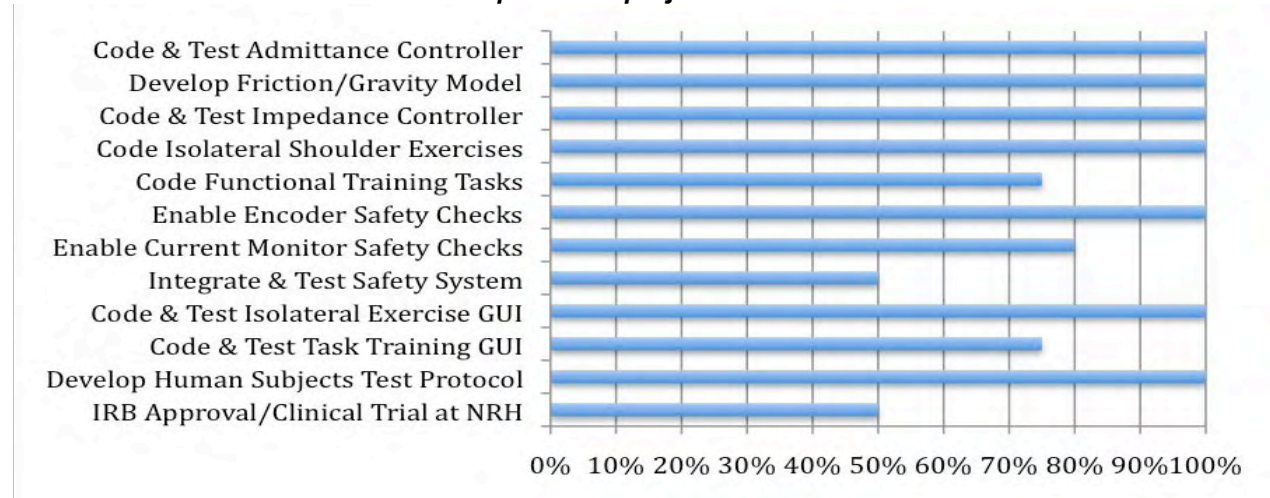
3.3.2 Exoskeleton therapy testing

We were not able to conduct the clinical pilot study at NRH for programmatic as well as technical reasons. The PI for the clinical study, Dr. Joseph Hidler, left the Catholic University of America in September 2008 before we were ready to conduct the study. This caused CUA to terminate their contract, and there were insufficient funds remaining to reissue another contract to MedStar. In addition, we could not meet our human subjects safety criteria due to higher than anticipated electronic noise in current monitoring channels in the safety system. This would require further time and resources to sufficiently address.

3.4 Milestones

The milestones for the above tasks and their degree of completion are shown in Table 3. Most tasks were completed except for full integration of the safety system and the clinical testing due to reasons discussed earlier. In addition, there were also unanticipated tasks, such as the replacement of the upper arm links, which detracted from resources needed to complete tasks in the statement of work causing delays on the path to clinical testing.

Table 3: Completion of project tasks/milestones.



4 Key Research Accomplishments

The key research accomplishments for the project are listed in bulleted form below:

- Developed and implemented a composite control architecture
 - shoulder rotation controller for the isolateral shoulder exercises
 - impedance controller for the functional training exercises
 - PD controller to drive the scapula based on humerus elevation
- Developed and tested exercise protocols
 - isolateral shoulder exercises (lateral raise, ab/adduction, rotation)
 - functional training protocols (wall painting, reaching task)
- Developed graphical interfaces for stroke rehabilitation
 - Virtual wall painting task
 - Balloon popping (reaching) task
- Developed dynamic model of exoskeleton for feedforward control
 - gravity compensation based on mass model
 - friction model for each actuator using velocity servoing tests
- Drafted command GUIs for inputting parameters
 - isolateral shoulder exercises
 - functional training tasks
- Developed clinical GUI for telemetry feedback
 - Position of arm (joint, Cartesian)
 - Elbow and wrist force sensors (force, torque)
- Implemented single fault-tolerant safety system
 - absolute/incremental encoder comparison checks
 - motor torque command/current monitor comparison checks

- Wrote task protocol for testing exoskeleton on human subjects
 - submitted and approved by MedStar IRB
 - submitted and approved by USAMRMC HRP

5 Reportable Outcomes

The kickoff meeting for this grant took place on March 6, 2008, and the presentation is included in Appendix 8.1. The major publishing deliverables for this project are two conference papers, four symposia presentations, and test protocol materials submitted to the MedStar Institute Review Board. We were invited to take part in the IEEE/EMBS Spring Symposium on "Technology for the Golden Years" held at the University of Maryland in May 2008 (see flyer in Appendix 8.4) in which we gave a presentation and live demonstration of the exoskeleton. Approximately 100 people from academia and industry attended the symposium, and the demo was featured in the IEEE Scanner highlighted. In addition, we gave a live demonstration of the exoskeleton at the University of Maryland Bioengineering Day in April 2009. Presentations on rehabilitation using exoskeletons were also given at the National Strength and Conditioning Association Pennsylvania State Strength & Conditioning Clinic at Juniata College in June 2008 and July 2009. Copies of the documents, presentations, and media publicity are provided in the appendices. We also submitted two SBIR proposals on modular exoskeleton design to the Department of Defense and the National Science Foundation in 2008 toward the goal of technology commercialization of the exoskeleton, but neither proposal was funded.

5.1 Publications

- *IEEE International Conference on Robotics and Automation*, May 22, Pasadena, Calif., regular paper: "Controlling Shoulder Impedance in a Rehabilitation Arm Exoskeleton" (Appendix 8.2)
- *IEEE/RSJ Int. Conf. on Intelligent Robots and Systems*, Oct. 11-15, 2009, St. Louis, regular paper: "Virtual Task Training using the MGA Exoskeleton", C. Carignan, J. Tang, S. Roderick (Appendix 8.3)

5.2 Presentations

- *TATRC Grant Kick-off Meeting*, March 6, 2008, National Rehabilitation Hospital, Washington, DC (Appendix 8.1)
- *IEEE Spring Symposium on Technology for the Golden Years*, May 10, 2008, University of Maryland, College Park, invited presentation: "Robotics for Strength Training and Rehabilitation" (Appendix 8.4-6)
- *NSCA PA State Strength & Conditioning Clinic*, 28 June 2008, Juniata College, PA, invited presentation: "Robotic Exoskeletons for Strength Training and Rehabilitation" (Appendix 8.7)
- *Booz-Allen-Hamilton Emerging Technologies Focus Group*, 8 May 2009, McLean, VA, invited webcast presentation: "New Technologies for Treating Shoulder/Arm Injury: The MGA Exoskeleton" (Appendix 8.9)
- *NSCA PA State Strength & Conditioning Clinic*, 10 July 2009, Juniata College, PA, invited presentation: "Shoulder Exercise and Rehabilitation with a Robotic Arm Exoskeleton" (Appendix 8.10)

5.3 Expositions

- Fischell Bioengineering Festival, University of Maryland, College Park, April 2009, live demonstration (Appendix 8.8)
- TATRC Advanced Medical Technology Exposition (OASIS), Fort Detrick, June 17-18, 2009, on display as part of Georgetown University ISIS Center exhibit (Figure 14)

5.4 IRB Documents

- *MedStar IRB approval for clinical trial (Appendix 8.11)*
- *Human Subjects Test Protocol (Appendix 8.12)*

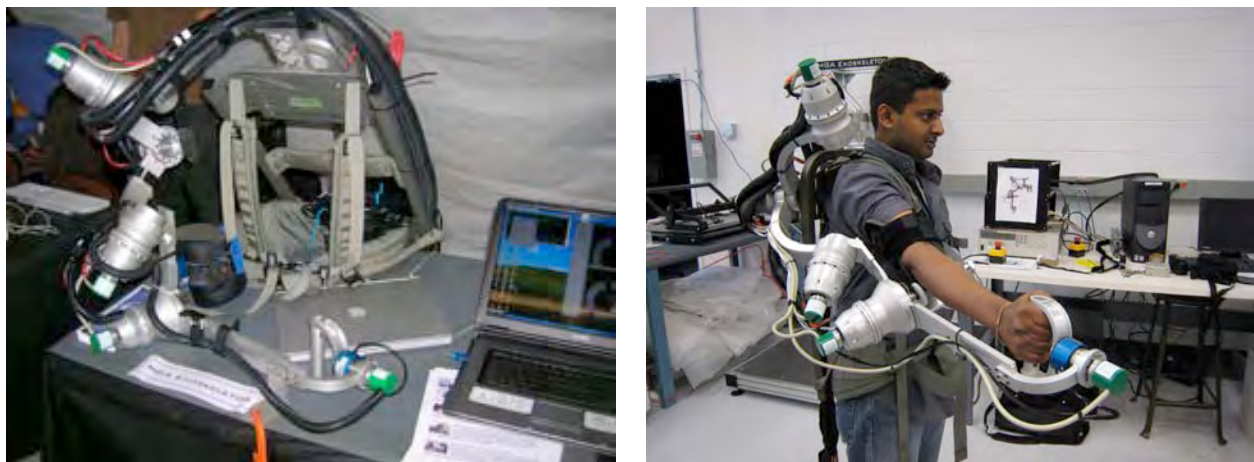


Fig. 15: The MGA Exoskeleton shown on display in the ISIS booth at OASIS Exposition (left) and deployed on subject (right).

6 Conclusions

The MGA Exoskeleton project has continued to lay ground breaking work in the development of robotic therapy tools for clinics of the future. We made significant progress on all fronts as outlined under the section on Key Research Accomplishments. We are pleased that we were able to nearly complete all of our project milestones except for the clinical study as discussed earlier, and our immediate goal is to seek further funding to complete the initial trial.

Although the first year of this research project was highly successful, we encountered a number of problems that took additional resources to address and thus prevented us from performing the initial pilot study. The following highlights the more critical issues:

- (1) New upper arm links needed to be designed and fabricated, and the original mechanical designer for the exoskeleton was hired as an independent contractor to perform this work. Fees to support his time and to fabricate the new links were not in the original budget.
- (2) The current monitoring signal from the motor amplifiers was very noisy, which made it difficult to use as a check against the current command data. This discrepancy has caused significant delays in bringing the safety system on line.
- (3) Gravity and friction models of the exoskeleton needed to be generated for feedforward

compensation in the impedance controller. This took much more time than originally anticipated as it required dismantling the exoskeleton to velocity servo the motors for friction testing and developing a gravity model to obtain precise mass parameter estimates.

(4) It was discovered that there are no good open source toolkits available for developing virtual reality graphics for building graphics for the functional training protocols. Therefore, we needed to develop our own repository of graphics tools using QT3, which took more time than anticipated.

(5) Control software development using the current architecture proved exceedingly difficult because it was developed for a robotic manipulator, not an exoskeleton. It was never intended to accommodate multiple force sensors or composite control.

We are currently applying to continue this effort under another grant. Our near term goals will focus on development that will bring the exoskeleton to a clinical operational status. The command GUIs will be converted to more user-friendly panels, and the telemetry will be graphical rather than text-based. The collection of data will be more automated and processed into standard therapy metrics. The safety system will be augmented to allow the clinician to input anatomical workspace/loading limits to enhance patient safety. The conversion of the software system to Orocos will yield a more robust architecture that is easier to modify. Finally, the multi-session clinical trial will compare the effectiveness of isolateral shoulder exercises performed with the exoskeleton to those done manually.

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8 Appendices

8.1 Presentation: "Rehabilitation of the Upper Extremity using a Robotic Arm Exoskeleton", Grant Kickoff Meeting, March 2008



Research Grant Review

Rehab Arm Exoskeleton

March 6 2008



Rehabilitation of the Upper Extremity using a Robotic Arm Exoskeleton

Grant Kickoff Meeting

Prime: Georgetown University

Sub: University of Maryland
Catholic University of America

March 6, 2008



Research Grant Review

Rehab Arm Exoskeleton

March 6 2008



Problems to be Solved

In the U.S., 15 million people seek medical care for the shoulder each year making it the #1 Injured joint in the upper extremity!

Orthopedic Therapy

rotator cuff tear, dislocated shoulder, tendonitis, shoulder separation, capsule tear, frozen shoulder, bursitis,

Short Term

Neuro-Rehabilitation

>700,000 strokes occur per year; now 5 million survivors



Longer Term

Prosthesis Training

500+ soldiers need to learn how to adapt to prostheses



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Solution: Arm Exoskeleton





Isolation Therapy **Functional Rehabilitation**



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Exoskeleton Description



- **Six degrees of freedom:**
 - scapula elevation (1)
 - shoulder rotation (3)
 - elbow flexion (1)
 - forearm pronation (1)
- **Torque output:**
 - 137 N-m at scapula
 - 137 N-m at shoulder
 - 69 N-m at elbow
 - 0 N-m at wrist
- **Passive adjustable links:**
 - clavicle (19.5-26.8 cm)
 - upper arm (27.2-31.2 cm)
 - forearm (23.0-32.0 cm)
- **Range of Motion**
 - shoulder flex/ext (147°/46°)
 - shoulder abd/add (105°/75°)
 - shoulder rotation (105°/75°)
 - elbow flex/ext (142°/0°)
 - forearm pro/sup (180°/180°)

Maryland-Georgetown-Army (MGA) Exoskeleton

- built in 2005 for surgical rehab under TATRC grant



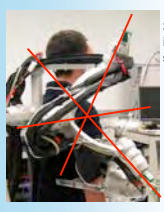
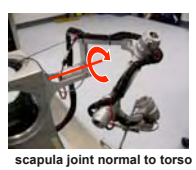
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Key Kinematic Design Features

3-axis intersecting shoulder

scapula joint normal to torso



passive link adjustments



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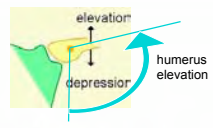
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Scapula-Humeral Rhythm

Refers to the elevation of the shoulder glenohumeral joint (GH) that occurs as the humerus (upper arm) rises



- Caused by rotation of the scapula for elevations below 90°
- GH joint moves on surface of sphere with clavicle radius ~15 cm



If this motion is not tracked, then the exoskeleton and human shoulder joints will become misaligned causing unnatural motion and pain.



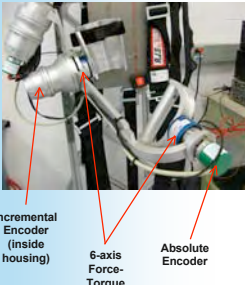
Scapula Rotation Video



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Sensors and Actuators



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ACTUATOR OUTPUT			
Arm Joint	Human (N-m)	MGA (N-m)	
Sc Elev/Dep	?	±137	
Sh Flex/Ext	115/110	±137	
Sh Abd/Add	134/94	±137	
Sh Med/Lat	-	±137	
Elb Flex/Ext	72/42	±69	
Fore Pro/Sup	9/7	-	

SENSORS			
Arm Joint	Incr. Enc.	Abs. Enc.	F/T Sensor
Scap	X	X	-
Shldr. 1	X	X	-
Shldr. 2	X	X	-
Shldr. 3	X	X	-
Elbow	X	X	X
Wrist	-	X	X



Human-Robot Interaction



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- ❑ Exercise therapy can require the application of a large amount of force or torque
- ❑ There are multiple points of contact between the human and exoskeleton
- ❑ Exercise protocols may dictate different combinations of position and force-controlled joints
- ❑ Exoskeletons are at the extreme end of safety-critical robotic systems



Current Robot Safety Standards

STAY OUT OF THE ROBOT'S WORKSPACE!

-ANSI/RIA R15.06



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Potential Hazards

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- A) The patient moves outside their safe position range
- B) The patient moves at an excessive velocity
- C) The exoskeleton applies excessive torque to the patient, or conversely, the patient applies excessive torque to the exoskeleton



Project Safety Criteria

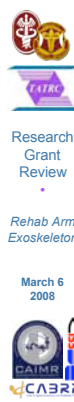
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- ❑ The system will be able to detect **any single** failure event and autonomously enter a safe state
- ❑ Safe state is either:
 - ❑ actively holding position and not exerting any force on the patient
 - ❑ complete power-down of the exoskeleton
- ❑ Design is based on approach certified by NASA for a robot flying on the Space Shuttle (only 1 failure in 1000 hours of operation)



Why Computer-Based Safety?

- ❑ While the hardware design can enhance safety, it cannot ensure it
- ❑ Computer monitoring is necessary to reliably determine excess velocities and forces
- ❑ Events happen too quickly to rely on a human operator to intervene
- ❑ The **operator** is also the **patient**!



Safety Design Process

```

graph TD
    A[System design] --> B[Preliminary hazard analysis]
    B --> C[Fault tree analysis]
    C --> D{Evaluate project safety criteria}
    D -- FAIL --> E[Modify system design]
    E --> A
    D -- PASS --> F[System design complete]
    
```

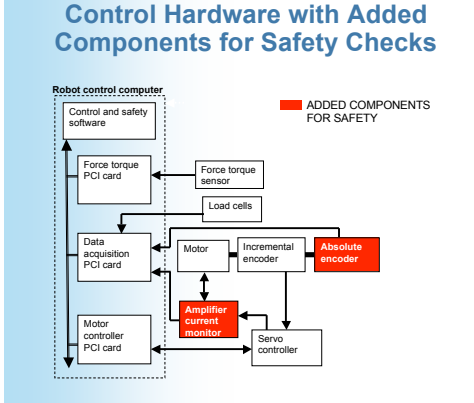
identify potential hazards (accidents)

failure sequence leading to hazard

can single failure cause hazard?



Control Hardware with Added Components for Safety Checks





Project Task Description

```

graph LR
    A[Select Exercise Tasks] --> B[Exercise Protocol Design]
    B --> C[Control/GUI Software Development]
    C --> D[Manual Therapy Assessment]
    D --> E[Pilot Testing of Human Subjects]
    E --> F[Complete Study]
    
```

TASK 1

TASK 2

TASK 2/3

TASK 3



Task 1: Design shoulder therapy protocols for the exoskeleton.

ISOLATERAL



shoulder abduction



"wall" push-up

- simple, isolated joint motion
- emphasis on maximum load
- builds muscle strength

FUNCTIONAL

PNF D1 Pattern



ADL Task



- complex motion mimics task
- emphasis on proper movement
- builds coordination & stability



Movement Modes

MOVEMENT MODE	MUSCLE GRADE	PATIENT ROLE	THERAPIST ROLE
Passive	0, 1	no effort	move limb
Active	2, 3	move limb	no force applied
Isometric	4, 5	maximum effort	immobile
Isokinetic	4, 5	maximum effort	apply constant velocity
Isotonic	5	move load	apply constant load

DEFINITIONS:

Isotonic - Subject moves against constant resistance (is lifting a set weight); this can result in either a concentric (shortening) or eccentric (lengthening) muscle contraction

Isometric - machine is static allowing isometric strength to be tested in any given configuration

Isokinetic - machine produces velocity-controlled active motion; subject develops resistance only if their effort meets or exceeds the velocity of the device

Exercise Decomposition

```
graph TD; A[Movement Mode] -- "Active, Isotonic" --> B[Resistance Profile]; A -- "Isometric, Isokinetic, Passive" --> C[Speed Profile]; B -- "Impedance" --> D["Z_des(s)  
Mass, Stiffness, Damping"]; C -- "Trajectory" --> E["x(t), ω(t)  
Rotational, Linear, Diagonal"]; B --> C; D --> E;
```

The diagram illustrates the process of Exercise Decomposition. It starts with a box labeled "Movement Mode". From this box, two arrows lead to "Resistance Profile" and "Speed Profile". The arrow to "Resistance Profile" is labeled "Active, Isotonic", and the arrow to "Speed Profile" is labeled "Isometric, Isokinetic, Passive". From "Resistance Profile", an arrow labeled "Impedance" leads to a box containing the mathematical expression $Z_{des}(s)$ and the text "Mass, Stiffness, Damping". From "Speed Profile", an arrow labeled "Trajectory" leads to a box containing the mathematical expression $x(t), \omega(t)$ and the text "Rotational, Linear, Diagonal". Additionally, there is a vertical arrow pointing from "Resistance Profile" down to "Speed Profile", and a horizontal arrow pointing from "Resistance Profile" to the right, which then leads to the "Trajectory" box.

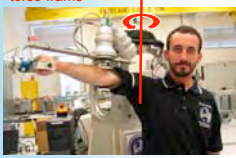
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Example Isolateral Exercises

torso frame



humeral frame



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```

graph TD
    EP[EXERCISE PROTOCOL] -- decompose --> CS[CONFIGURATION SPACE]
    CS -- "input parameters" --> CC[COMPOSITE CONTROLLER]
    CC -- "joint activation" --> JC[JOINT CONTROLLER]
    JC -- "GO" --> EP
    JC -- "safety monitoring" --> CS
  
```

Task 2: Develop control system to implement protocols.

The diagram illustrates a control system architecture for implementing protocols, involving four main components and their interactions:

- EXERCISE PROTOCOL** (Blue box) connects to **CONFIGURATION SPACE** (Orange box) via the process **decompose**.
- CONFIGURATION SPACE** connects to **COMPOSITE CONTROLLER** (Black box) via **input parameters**.
- COMPOSITE CONTROLLER** connects to **JOINT CONTROLLER** (Green box) via **joint activation**.
- JOINT CONTROLLER** connects back to **EXERCISE PROTOCOL** via **GO** (represented by a large upward arrow).
- JOINT CONTROLLER** also feeds back into **CONFIGURATION SPACE** via **safety monitoring** (represented by a red circular arrow).

Logos at the bottom left include the University of California, Irvine (UCI) and the Center for Advanced Motor Behavior (CMB) at the University of California, Riverside (UCR).

Why Distributed Control?

- ❑ Different muscle groups (and joints) are targeted during therapy
- ❑ Exercises require different types of control
 - ❑ resistance-based (e.g. strengthening)
 - ❑ position-based (e.g. stretching, functional training)
- ❑ Joints must be controlled concurrently subject to biomechanical constraints



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Impedance vs. Admittance Control

Impedance is defined as:

$$F = Z \dot{x}$$

■ Advantages

- No force sensing
- Stable at low impedance
- No inverse kinematics

■ Disadvantages

- Need model feedforward
- Direct torque commands

Admittance is defined as:

$$\dot{x} = Y F$$

■ Advantages

- No model feedforward
- Stable at high impedance
- High accuracy

■ Disadvantages

- Need force sensor
- Need inverse kinematics

Step 1. Find “Configuration Space”

ISOLATERAL EXERCISE:
 Scapula (1) +
 Shoulder (3) +
Elbow Pitch (1)
 = 5 DOFs

PNF D1 EXERCISE:
 Scapula (1) +
 Wrist (3) +
Elbow Orbit (1)
 = 5 DOFs

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elbow F/T sensor

wrist F/T sensor

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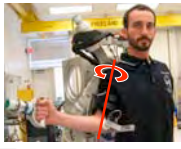


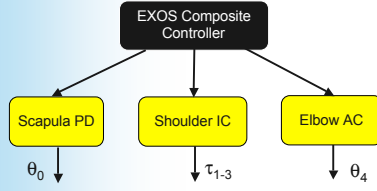
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Step 2: Select Subcontrollers

EXAMPLE: ISOLATERAL

- Desired shoulder rotation axis/impedance selected
- Elbow flexion is free (user force-accommodation)
- Scapula rotation governed by biomechanical model





EXOS Composite Controller

Scapula PD → θ_0

Shoulder IC → τ_{1-3}

Elbow AC → θ_4



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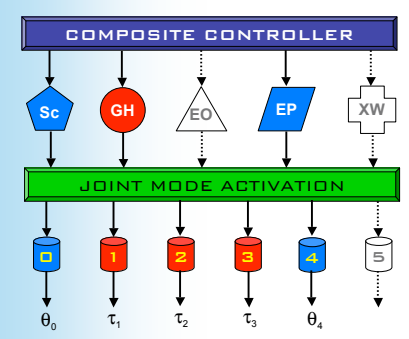
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Step 3. Command Joints



COMPOSITE CONTROLLER

Sc GH EO EP XW

JOINT MODE ACTIVATION

θ_0 τ_1 τ_2 τ_3 θ_4

*Sc=scapula, GH=glenohumeral, EO=elbow orbit, EP=elbow pitch, XW=wrist

IMPEDANCE ADMITTANCE INACTIVE



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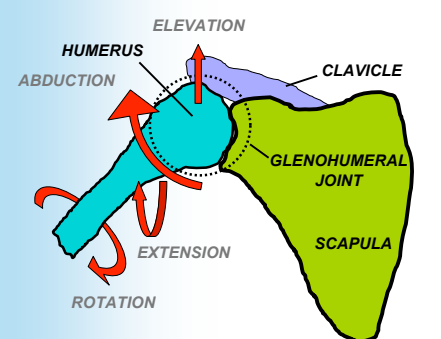
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How can shoulder torque be determined?



HUMERUS, CLAVICLE, GLENOHUMERAL JOINT, SCAPULA



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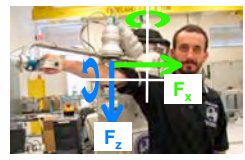
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Use elbow and wrist force sensors



F_y

compute inner/outer rotation torque from wrist force sensor



F_x , F_z

compute abduction/adduction and flexion/extension torques from elbow force sensor



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Task 3: Pilot study with human subjects to validate operation

PURPOSE:

- validate operation on a small number of subjects with a wide range of arm geometries
- not to assess outcome or compare robotic with manual therapy

Specifically:

- Determine device efficiency, comfort, control limitations.
- Compare measurements of arm kinematics and kinetics during manual and exoskeleton therapy.
- Examine user-friendliness of clinical interface during an actual therapy session.



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Manual Motion/Strength Testing

- Motion Analysis
 - range of motion (ROM) tasks
 - functional tasks
 - diagonal movement tasks
- Strength Testing
 - maximum voluntary isometric (MVIC)
 - maximum voluntary isokinetic (MVIK)






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Patient Movement Ratings

Rating	Strength	Description
0	0%	cannot contract muscle
1	10% (trace)	trace of muscle contraction but cannot move limb
2	25% (poor)	can perform ROM* in a gravity eliminated position
3	50% (fair)	can perform ROM against gravity but no external resistance
4	75% (good)	can perform ROM against gravity and with moderate resistance
5	100% (normal)	can perform ROM against gravity and full resistance

*ROM = Range of Motion

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Protocol Matrix

Exercise Tasks	Movement Mode				
	Passive	Active	Isotonic	Isometric	Isokinetic
Strength Testing					
Flexion/Extension			X	X	X
I/E Rotation			X	X	X
Ab/Adduction			X	X	X
Range of Motion					
Elevation in all planes	X	X	X		
I/E Rotation	X	X	X		
Functional Tasks					
Reaching		X	X		
X-body movement		X	X		
Box lift		X	X		
PNF Diagonal Patterns ¹					
D1 Flex/Ext	X	X	X		X
D2 Flex/Ext	X	X	X		X

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Test Procedure

1. Subject completes informed consent procedures
2. Screening PT exam is performed to rule out any overt limitations
3. Biodex test session is performed to determine AROM and strength for strength exercises
4. Subjects set up for motion analysis
5. Subject performs AROM for functional exercises (D1 and D2 patterns)
6. Subject dons exoskeleton and practices movements
7. Exoskeleton testing for selected exercises

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Challenges

- **Technical challenges**
 - Comfortable restraint system that will keep the upper torso stabilized and shoulder aligned
 - Developing the software and database for all of the subcontrollers
 - Getting accurate current monitor data for the safety check on the motor amplifiers
- **Requirements challenges**
 - Getting all of the controllers to work for a wide range of resistance parameters
 - Developing the graphical user interfaces for the clinician
- **Programmatic challenges**
 - Coordinating efforts in three different locations
 - Getting through two local IRBs and the TATRC human subject review board within 1 year

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Proposed Change #1: Abandon development of impedance control modules

- Requires the development of accurate friction and gravity feedforward models which is very difficult for non-backdrivable (geared) systems
- Preliminary experiments indicate that the admittance control modules perform well even at low impedances
- Impedance controllers output torque commands, which is not as safe as position commands

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Proposed Change #2: Downselect exercise tasks to iso-lateral and ADL only

- PNF training is not as functional as most ADL tasks
- Exoskeleton is not portable so cannot do X-body movement right now
- Perform more reaching movements which are common in stroke rehabilitation
- Can focus more effort on developing user-friendly graphical interfaces
- Need to submit an IRB protocol as soon as possible for end-of-year testing

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Successes to Date

- **Composite Control Architecture Design**
 - pioneered application to an exoskeleton device
 - introduced in Nov'07 at the ASME World Congress
- **Several Controllers Developed and Tested**
 - admittance controllers for shoulder, elbow pitch, elbow orbit, and hand translation
 - shoulder impedance controller (w/o model feedforward)
- **Demonstrations Completed**
 - isolateral shoulder rotation exercises
 - hand translation tasks
 - elbow orbit self-motion
- **Human Interfaces**
 - two prototypes developed for elbow brace
 - shoulder restraint system using race-car harness
- **Safety System**
 - encoder redundancy check integrated into system
 - first preliminary hazard analysis performed for a rehabilitation arm exoskeleton



Schedule

Task Description	15 Jan 08	15 Apr 08	15 July 08	15 Oct 09	15 Jan 09
Project reviews		◆ PDR		◆ PLR	
Task 1 – Exercise Protocols					
Shoulder biomechanics					
Isolateral exercise design					
Functional exercise design					
Trajectory Generation					
Clinical Interface					
Task 2 – Control System					
GH admittance controller					
XW admittance controller					
Impedance selection					
Safety system integration					
Task 3 – Human Testing					
Recruit subjects					
Manual strength tests					
Exoskeleton testing					



Additional Project Information

Lab/Company/Group: Georgetown University ISIS Center

Principal Investigator: Dr. Craig Carignan

Government COR: Dr. Sylvain Cardin

Government Project Officer: Ms. Ashley Glenn

Contract Instrument: Cooperative Agreement

Period of Performance: 15 January 08 - 14 February 09

Contract Specialist: Ms. Michelle Maldonado

Date Initiated: 15 January 08

EDMS#: 3387

Contract #: W81XWH-08-2-0010



WHAT'S NEXT???



Now is a time to storm.
-W. Shakespeare

8.2 Paper: "Controlling Shoulder Impedance in a Rehabilitation Arm Exoskeleton", International Conference on Robotics and Automation (ICRA), Pasadena, May 2008

Controlling Shoulder Impedance in a Rehabilitation Arm Exoskeleton

Craig R. Carignan, Michael P. Naylor, and Stephen N. Roderick

Abstract—A control methodology is developed for modulating shoulder impedance in an arm exoskeleton during physical therapy. Setting the remote center of compliance at the shoulder will allow the exoskeleton to enact resistance training protocols that strengthen the rotator cuff and other joint musculature supporting the shoulder complex. The rotational kinematics for the shoulder are first derived, and then the torques applied at the shoulder are estimated using force sensors placed at the hand and elbow interfaces. Impedance and admittance control schemes are both developed for realizing isolateral strengthening exercises, and some preliminary experimental results are presented for implementation on an arm exoskeleton currently under development.

I. INTRODUCTION

In most manipulator applications, the remote center of compliance is located at the tool tip and controlled using force readings from a sensor located in the wrist. Likewise, exoskeletons developed for virtual reality (VR) applications usually reflect forces at the hand resulting from interaction with virtual environments [1]. This type of force reflection can be met by using a central controller to simultaneously move all of the exoskeleton joints to exert a desired force at the hand. However, this strategy is ineffective for rehabilitation applications where individual arm joints are being targeted for physical therapy.

In a rehabilitation arm exoskeleton, the remote center of compliance is any joint-muscle group in the arm being targeted for therapy. For example, during the shoulder extension exercise shown in Fig. 1, the resistance about the shoulder lateral axis needs to be controlled by the exoskeleton over the range of motion. An additional complication is that a force-torque sensor placed at the wrist or hand does not alone provide enough information to determine the torques in the shoulder joint. Therefore alternative force sensor emplacement strategies also need to be investigated.

In this article, dual impedance-admittance control approaches are investigated for modulating impedance in the shoulder joint during exercise therapy. The shoulder-axis can either be fixed or vary with configuration of the arm. Impedance control schemes are explored that use force-torque sensors placed at the hand and elbow to estimate the

applied forces. Some preliminary test results are presented for implementing impedance control for realizing isolateral exercises.



Fig. 1. The MGA Exoskeleton has five powered joints including a three-axis intersecting shoulder and a scapula elevation joint.

II. PREVIOUS WORK

Most arm exoskeletons built to-date were developed as either force-reflecting master arms for teleoperation or as haptic devices for virtual reality (VR) applications [1]. In these applications, “contact” forces are imparted at the handle of the exoskeleton that replicate forces sensed by a slave arm or by interaction with a virtual environment. A basic form of impedance control is usually implemented in which the Cartesian forces at the handle are mapped into joint torque commands using the Jacobian [10]. This approach eliminates the need to compute the inverse kinematics and is stable at low impedances.

The main drawback of impedance control is that good force replication at the handle requires compensation of the natural dynamics of the exoskeleton, such as gravity loading and drive friction. A force loop wrapped around the force sensor can reduce unmodeled effects [2], but it can also easily destabilize the system. The *Exoskeleton Arm-Master* [1] and the *L-Exos Exoskeleton* [7] are classic examples of exoskeletons that use this approach.

An alternative approach called “admittance” control has primarily been used to control manipulators used as large-reach haptic devices [3], [5]. In this approach, the sensed force at the handle is used as the input to a desired impedance

This work was supported by the U.S. Army Telemedicine and Advanced Technology Research Center (TATRC), Ford Detrick, Maryland

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M. Naylor and S. Roderick were faculty research associates with the Space Systems Laboratory, University of Maryland, College Park MD 20740 USA; Naylor is now a robotics engineer with Accuray, Inc., Sunnyvale CA mnaylor@accuray.com and Roderick is a consulting engineer snrkiwi-2007@yahoo.com

model, which outputs a desired motion to be imparted at the hand. The Cartesian position is mapped into joint position commands using the inverse kinematics, which are then input to a proportional-derivative (PD) servocontroller to drive the joints to the desired position.

The main advantage of the admittance approach is that the high gains of the joint position servo-loop are used to reject unmodeled dynamics without resorting to model feed-forward. However, it has the major drawback of instability for high admittance (low impedance), which is the opposite of impedance control [9]. The *Sensor Arm* [11] is an example of an exoskeleton implementing this approach, and the more recent *ARMin Exoskeleton* [12] appears to be able to operate in either admittance or impedance mode.

Almost all exoskeleton designs incorporate a six-axis force sensor at the gripper for determining forces applied at the hand [7]. Some designs use force-torque sensors mounted on the links to obtain forces at other locations along the arm. The *ARMin* reacts loads to the distal end of the forearm link through force-torque sensor attached to a wrist cuff [12]. The *Sensor Arm* [11] uses concentric rings connected by strain gauges to determine forces applied by the arm, where the inner ring is secured to the limb using an inflatable bladder. Attempting to use torque cells at the exoskeleton joints to derive torques in the human joints is fraught with difficulties because the exoskeleton joints do not align with the human joints and the internal joint dynamics corrupt the readings. Thus this approach is rarely used.

III. SHOULDER KINEMATICS

The human shoulder (glenohumeral) joint is a ball-and-socket joint capable of abduction/adduction, flexion/extension, and internal/external rotation as shown in Figure 2. In addition, the glenohumeral joint translates along the surface of a sphere as the humerus (upper arm) elevates producing both shoulder elevation/depression and pronation/supination (in and out of plane). The ability to replicate this “scapulo-humeral rhythm” is key to realizing natural movement of the shoulder. The exoskeleton uses three serially-connected rotational joints with intersecting axes to replicate this motion. However, the axes of rotation do not always correspond to the anatomical abduction-flexion-rotation axes.

Figure 3 shows the kinematic configuration of the MGA Exoskeleton along with Denavit-Hartenburg (D-H) link frame assignments [6]. The D-H parameters for the kinematics are given in Table I except for the scapula joint 0 which is mounted perpendicular to the coronal plane. The angle between the z_0 and z_1 axis is 30° , and the angle between the z_3 and z_4 axis is 45° . The scapula, upper arm, and forearm links all have passive sliding joints to accommodate variable subject geometry: $L_S = 14.0 - 25.6$ cm, $L_U = 27.3 - 31.3$ cm, and $L_F = 30.0 - 39.0$ cm. The displacement of the force sensors along the z-axis of their respective frames are $L_{S_h} = 5.72$ cm and $L_{S_e} = 7.62$ cm.

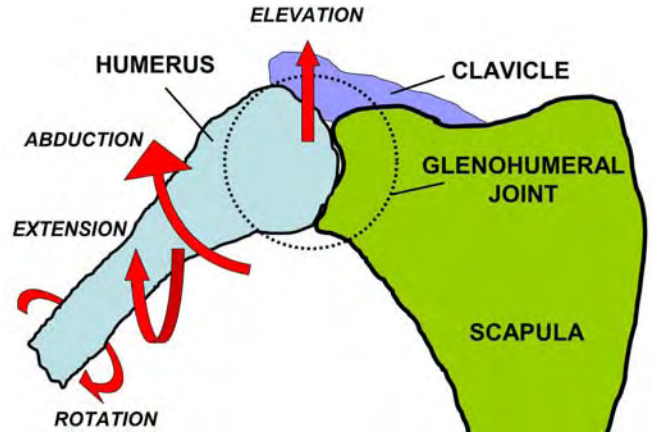


Fig. 2. Movements of the human arm and shoulder girdle.

TABLE I
D-H PARAMETERS FOR THE MGA EXOSKELETON.

link i	a_{i-1} (cm)	α_{i-1} (deg)	d_i (cm)	θ_i^* home (deg)
1	0	+30	0	+90
2	0	-90	0	-105
3	0	+90	$\sqrt{2}L_U$	-90
4	0	-45	$-L_U$	0
5	0	-90	L_F	0

A. Arbitrary Shoulder Rotation

Shoulder rotation is defined as the orientation of the upper arm frame $\{U\}$ with respect to the body frame $\{B\}$. Frame $\{U\}$ is co-located with frame $\{4\}$ but with the z_U -axis directed along the humerus away from the shoulder. It can thus be defined as a 45° rotation of frame $\{3\}$ about the x_3 -axis, i.e. ${}^3R_U = R_X(45^\circ)$, followed by a translation of $-L_U/\sqrt{2}$ along the z_4 -axis

$${}^B R_U = {}^B R_0 {}^0 R_3 {}^3 R_U \quad (1)$$

where ${}^B R_0 = R_X(-\theta_0)$. The shoulder orientation ${}^0 R_3$ relative to the base is determined by using the D-H Table to find the local link transformations ${}^i R_{i+1}$ and cascading the resulting rotation matrices for links 1-3. The direction of the humeral axis in the body frame $\{B\}$ is given by ${}^B \hat{z}_U$, the third column of ${}^B R_U$, which is used to compute the axis of rotation for internal/external shoulder rotation exercises.

B. Self-Motion Shoulder Rotation

During exercise involving translation of the hand, the free-axis of shoulder rotation is along a straight line from the shoulder to the wrist as shown in Figure 4. Because the axis passes through the wrist, rotation about this axis or “elbow orbit” produces no motion of the wrist and is thus referred to as “self-motion”. The elbow “orbit” angle ϕ is defined as the angle that the plane formed by the points S, E, and W makes with the reference plane defined by the reference vector, $\hat{v}$, and the shoulder-wrist vector, p_w [8].

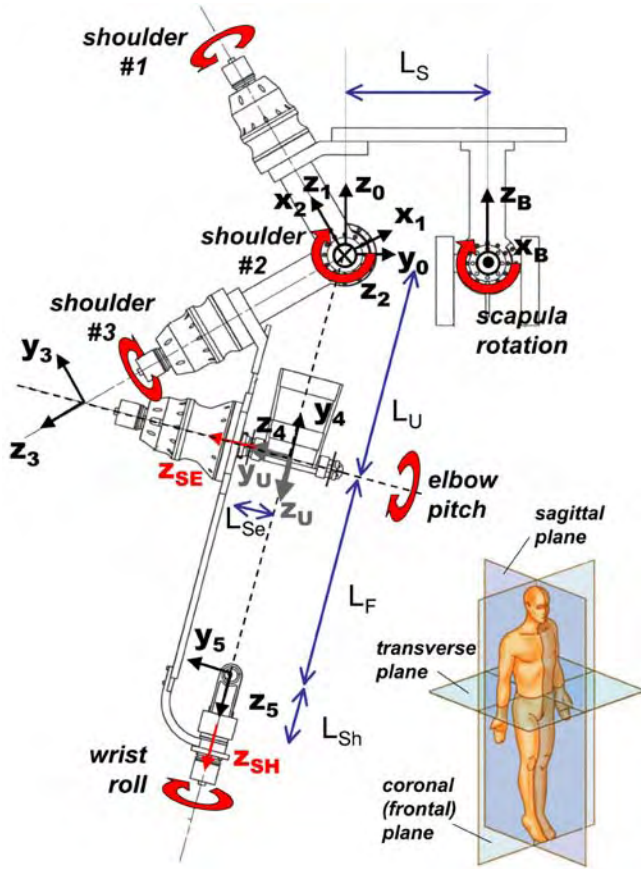


Fig. 3. MGA Exoskeleton link frame assignments shown in the frontal (coronal) plane. The exoskeleton joint axes are along the z_i -axes with rotations indicated by an arrow. The body planes are shown in the inset (<http://en.wikipedia.org/wiki/Image:BodyPlanes.jpg>).

Let the vectors from the shoulder to the wrist and elbow be defined as p_w and p_e , respectively, and let $\hat{v}$ denote an arbitrary fixed unit reference vector in frame 0. The roll angle of the SEW plane or “elbow orbit angle” is defined as the angle between p_p and p_ℓ

$$\tan \phi \equiv \frac{\hat{p}_w^T (p_\ell \times p_p)}{p_\ell^T p_p} \quad (2)$$

ϕ is calculated by using the forward kinematics to compute p_w and p_e and then performing the vector operation in (2) numerically.

IV. ISOLATERAL EXERCISE CONTROL

Iso-lateral exercises are those that occur around a single rotation axis of the shoulder and closely resemble those performed manually with dumbbells, rubber tubing, and exercise machines [13]. Examples of shoulder rotation exercises include internal/external rotation and shoulder abduction/adduction as shown in Figures 5 and 6, respectively. In isolateral exercises, the motion of the shoulder joints is determined by the motion of the upper arm. In self-motion exercises, the axis of rotation is automatically specified by the position of the wrist.

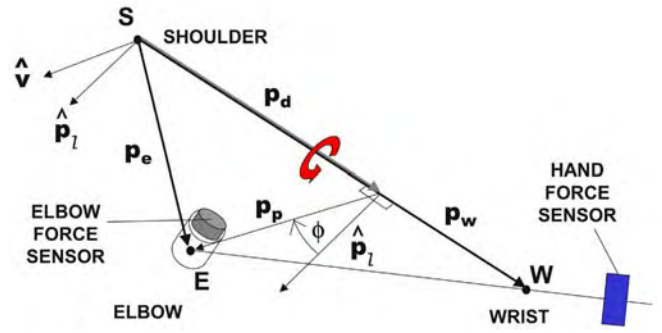


Fig. 4. Self-motion of the arm or “elbow orbit” occurs about a line from the shoulder to the wrist.

TABLE II
ISOLATERAL CONTROL EXERCISES.

Exercise	Plane of Motion	Rotation Axis	Azim./Elev.
Ab/Adduction	frontal	$[1, 0, 0]$	$90^\circ / 0^\circ - 90^\circ$
Flex/Extension	sagittal	$[0, 1, 0]$	$0^\circ / 0^\circ - 90^\circ$
Ab/Adduction	transverse	$[0, 0, 1]$	$0^\circ - 90^\circ / 90^\circ$
Elevation	scapula	$[\sqrt{3}/2, 1/2, 0]$	$60^\circ / 0^\circ - 90^\circ$
Int/Ext Rotation	$\perp$ humerus	$\overline{SE}, {}^B z_U$	—/—
Elbow Orbit	$\perp$ shoulder-wrist	$\overline{SW}, {}^0 p_5$	—/—

Some common isolateral exercises are shown in Table II. The second column indicates the plane of motion, and the third column indicates the axis of rotation. The final column specifies the azimuth and elevation of the humerus during the exercise. Azimuth corresponds to the rotation about the longitudinal axis z_B (0° is straight ahead) and elevation is the angle the humerus makes with the longitudinal axis (0° is straight down).



Fig. 5. Exoskeleton shown performing external/internal rotation at about 90° elbow flexion.

Exercises are implemented using the modular “composite” control architecture shown in Figure 7 [4]. The exoskeleton joints are first parsed into mutually exclusive sets of subcontrollers based on the activation of human arm joints during



Fig. 6. Exoskeleton shown at 90° shoulder abduction.

the exercise: scapula (Sc), shoulder (GH), elbow orbit (EO), elbow pitch (EP), and wrist translation (XW). Only certain combinations are allowed; for example, shoulder GH/elbow pitch or wrist translation/elbow orbit are permitted, but not wrist translation/shoulder GH because they have overlapping joints. Each of these joint sets can be selected to operate in either impedance or admittance mode depending upon the desired impedance values. The joint servo modes are set by the composite controller to accept either position or torque commands from the corresponding subcontroller. The shoulder GH controllers are discussed in more detail below.

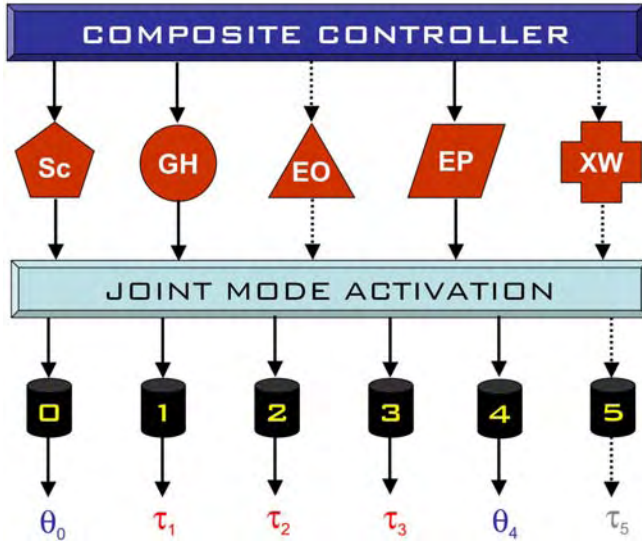


Fig. 7. The Sc Admittance, GH Impedance, and EP Admittance modules are shown here being enabled by the composite controller for a shoulder rotation exercise. The Sc and EP output scapula and elbow position commands, respectively, whereas the GH module outputs shoulder torque commands. A joint mode command of either “position” or “torque” is sent to each motor servo by the composite controller to enable the appropriate input. (Subcontrollers: Sc=scapula, GH=glenohumeral, EP=elbow pitch, EO=elbow orbit, XW=wrist translation.)

A. Shoulder Impedance Module

The shoulder impedance controller is primarily used for low resistance shoulder rotation exercises. The desired

impedance is multiplied by the angular velocity of the glenohumeral (GH) joint shown in Figure 8 to produce a desired Cartesian torque T_{des} . The desired torque and “sensed” torque are then “differenced” to form a torque error and multiplied by a feedback gain K_F . The desired torque and feedback error are then converted back to joint coordinates to produce a desired torque τ_{des} . The desired torque and feedforward compensation τ_{fwd} are then summed to form the control command τ to the motors.

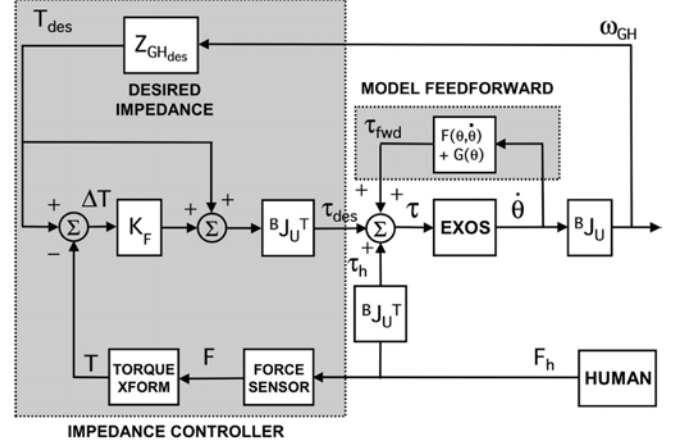


Fig. 8. Impedance controller used for shoulder axis rotation.

The desired stiffness and damping are set in $Z_{GH_{des}}$ to have the specified values about the axis of rotation and high values about the off-axes to maintain isolateral rotation. The z-axis of a rotation frame $\{C\}$ is aligned with the desired axis of rotation, and then ${}^B R_C$ is the transformation between the rotation frame and the body frame. Thus, the desired stiffness in $Z_{GH_{des}}$ can be found from

$$K_{GH_d} = {}^B R_C K_C {}^B R_C^T \quad (3)$$

where K_C is the stiffness in the rotation frame (same for damping). If the rotation is about the humeral axis, then the z-axis of the compliance frame aligns with the humerus longitudinal axis so that ${}^B R_C = {}^B R_U$.

B. Shoulder Admittance Module

The shoulder admittance controller is shown in Figure 9. The elbow and hand force torque sensors are used to derive the humerus and the azimuth-elevation torques. The desired admittance is then multiplied by either the humerus or az-el torques to produced the desired rotational velocity of the shoulder in the base frame, ω_d . The desired Cartesian velocity is then multiplied by the inverse Jacobian to obtain the desired velocities of the shoulder joints $\dot{\theta}_{S_d}$. The desired velocity is then integrated and fed into a joint PD controller to drive the exoskeleton joint angles to the desired positions. Since the torques in the human glenohumeral joint cannot be directly measured, the shoulder torque inputs in Fig. 9 must be estimated using force sensors mounted at the arm-exoskeleton interfaces. The estimation of shoulder torques is discussed in the next section.

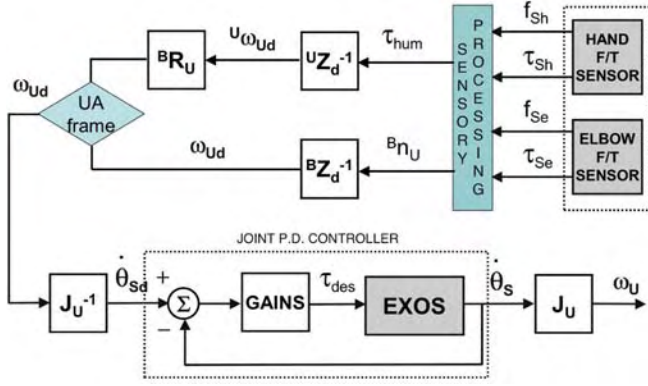


Fig. 9. The admittance controller for the shoulder uses force inputs from the elbow and hand force sensors to compute the commanded shoulder rotational velocity based on the desired admittance.

V. SHOULDER TORQUE ESTIMATION

The force sensors located at the hand and elbow interfaces can be used to estimate the shoulder torques for the admittance controller shown in Fig. 9. For general shoulder rotations, the shoulder torques can be decomposed into those perpendicular to the humeral axis and those about the humeral axis. The perpendicular torques are determined using the elbow sensor, and torques about the humerus axis are more accurately estimated using the hand sensor.

A. Azimuth/Elevation Torques

The shoulder azimuth and elevation torques are estimated by projecting the force and moment from the elbow sensor to frame $\{0\}$. The elbow force and moment in the sensor frame, f_{S_e} and n_{S_e} , are first converted to the upper arm frame using

$${}^U f_U = {}^U R_{S_e} f_{S_e} \quad (4)$$

$${}^U n_U = {}^U p_{S_e} \times {}^U f_U + {}^U R_{S_e} n_{S_e} \quad (5)$$

where ${}^U p_{S_e} = [0 \ 0 \ L_{S_e}]^T$ and ${}^U R_{S_e} = R_Z(45^\circ)$ represent the fixed position and orientation of the elbow sensor in frame $\{U\}$. The moment in frame $\{0\}$ is then found from (4) and (5) using

$${}^0 n_U = {}^0 p_U \times {}^0 R_U {}^U f_U + {}^0 R_U {}^U n_U \quad (6)$$

where ${}^0 p_U = {}^0 p_4$. The moment can then be converted to frame $\{B\}$ coordinates through pre-multiplying (6) by ${}^B R_0$.

B. Humeral Torque

The torque about the upper arm is found from the component of the hand force that is tangent to the humeral axis, i.e. the z_4 direction. The hand sensor is fixed to frame $\{5\}$ at a distance L_{S_h} along the z_5 -axis and oriented at an angle 45° about z_5 so that ${}^5 p_{S_h} = [0 \ 0 \ L_{S_h}]^T$ and ${}^5 R_{S_h} = R_Z(45^\circ)$. The hand sensor force in frame $\{4\}$ is found from

$${}^4 f_5 = {}^4 R_5 {}^5 R_{S_h} f_{S_h} \quad (7)$$

where f_{S_h} is the sensor reading. The humeral torque is found using the sensor's z-force and the perpendicular component of the forearm relative to the upper arm

$$\tau_{UA} = (L_F + L_{S_h}) \sin(\theta_4)^4 f_5 \cdot \hat{z} \quad (8)$$

where θ_4 is the elbow flexion.

C. Elbow Orbit Torque

The z-component of the elbow force sensor in f_{S_e} can also be used to determine the torque, τ_ϕ , exerted about the shoulder-wrist axis, p_w . The elbow orbit torque is calculated by taking the product of the z-component of the force and multiplying it by the moment arm

$$\tau_\phi \equiv |p_p| f_{S_e} \cdot \hat{z} \quad (9)$$

where p_p is the minimum distance from the elbow to $\overline{SW}$.

VI. SHOULDER EXPERIMENTS

Several experiments were conducted to validate the operation of the shoulder and elbow orbit admittance modules during simulated exercises. Since a feedforward model for the exoskeleton is still under development, the impedance module was not tested. The scapula joint was maintained at 0° throughout these tests.

A. Shoulder Abduction Experiment

The shoulder admittance controller was used to program a constant resistance during a lateral raise exercise in the scapula plane. The upper arm was initially oriented straight down by the side at 0° elevation parallel to z_B but with the x_U -axis rotated inward approximately 30° about the $+z_B$ -axis. The upper arm was then elevated about the x_U -axis to a horizontal position similar to that shown in Figure 6. The desired stiffness was set to $k_{diag} = [0 \ 500 \ 500]$ N-m/rad so that it was free to rotate about the x_U -axis but stiff in the off-axis directions. The desired damping was set to $b_{diag} = [100 \ 500 \ 500]$ N-m/rad/sec so that the desired impedance about the x_U -axis was pure viscous damping.

The resulting angular displacement and rate are shown in Figure 10. The angle decreases in magnitude as the humerus elevates to a horizontal position, and then reverses direction as it descends. The shoulder torque estimated using the elbow sensor is shown in Figure 11. The torque is predominantly about the rotational axis x_U and reaches a peak of about 20 rad/sec. The velocity during the abduction phase is approximately 0.2 rad/sec, which would be expected to produce a torque of approximately $b_d \omega = 20$ N-m which agrees with the actual values shown in Figure 11.

B. Self-Motion Experiment

In this experiment, the subject executes a pure elbow orbit maneuver by "rolling" the elbow about the shoulder-wrist line first counterclockwise and then clockwise as viewed from the shoulder. The desired elbow orbit impedance was set to be a pure rotational damping of $Z_{\phi_{des}} = 50$ N-m/rad/sec so that the exerted torque should be proportional

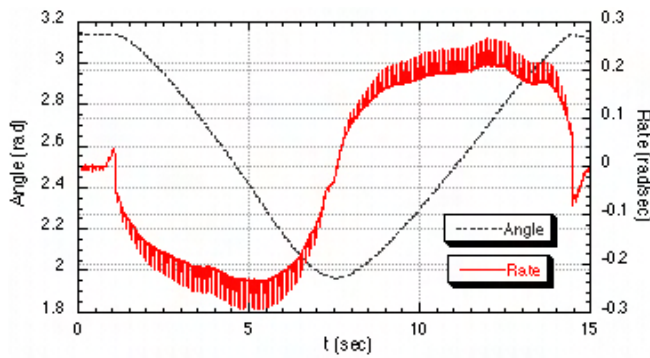


Fig. 10. Eigen-axis angle and rate during lateral abduction.

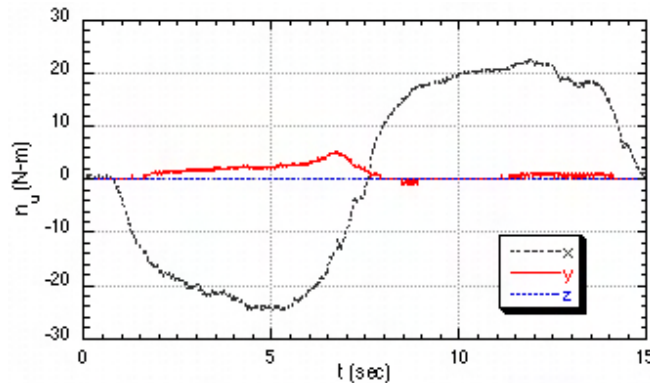


Fig. 11. Torques in the shoulder during lateral abduction.

to the rotational velocity. The resulting elbow orbit angle and torque are shown in Figure 12. The slope of the elbow orbit angle is approximately constant giving an angular velocity of about 0.1 rad/sec. The torque flips signs as the direction of rotation changes yielding a value of about 5 N-m during the maneuver.

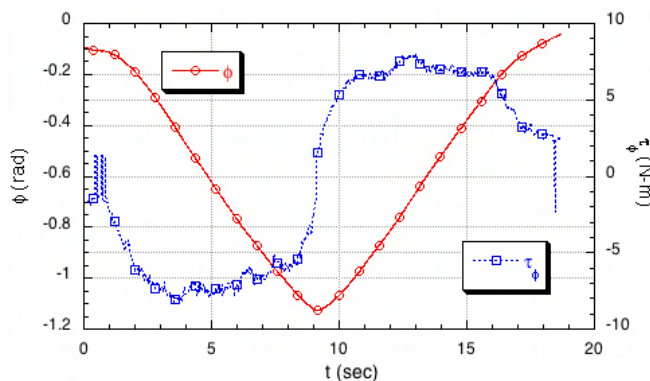


Fig. 12. Elbow orbit angle and torque for $b_\phi = 50$ N-m/rad/s during accommodation maneuver.

VII. CONCLUSION

Rotational kinematics were developed for controlling the shoulder joints of an arm exoskeleton for several isolateral exercise protocols. A torque estimation scheme based on dual force sensors was used to supply torque input to the shoulder

GH admittance controller. The admittance controller demonstrated good ability to track a pure damping impedance for isolateral rotation or elbow orbit, which does not rely on model feedforward. Although the shoulder GH impedance controller has also been coded, gravity and friction feedforward models need to be developed before the controller can be used.

Work is currently in-progress to fully develop the other control modules so that a full cadre of exercise protocols can be implemented. Impedance parameters are being determined for a variety of exercise protocols that take into account the human strength potentials over the range of motion. In addition, VR protocols are also being created to implement functional training and proprioceptive neuromuscular facilitation (PNF) patterns. After the protocols have been developed, clinical trials will be conducted and compared with results from manual therapy and passive exercise machines.

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8.3 Paper: "Development of an Exoskeleton Haptic Interface for Virtual Task Training," International Conference on Intelligent Robot Systems (IROS), St. Louis, October 2009

Development of an Exoskeleton Haptic Interface for Virtual Task Training

Craig Carignan, Jonathan Tang, and Stephen Roderick

Abstract—An exoskeleton haptic interface is developed for functional training in virtual environments. A composite control scheme enables a variety of tasks to be implemented, and a “Qt” graphics library is used to generate the virtual environment for the haptic interface at the hand and graphical user interfaces for input and telemetry. Inter-process communications convert telemetry from the exoskeleton into motion commands for objects in the virtual environment. A second haptic interface at the upper arm is used to control the elbow orbit self-motion of the arm during tasks. Preliminary results are reviewed for a wall-painting task in which the virtual wall stiffness and viscosity are generated using an admittance controller.

I. INTRODUCTION

The combination of virtual reality graphics with robotic force-feedback provides a powerful new tool for virtual reality (VR) training. In this scenario, simulated tasks with selectable parameters are generated on a computer display while the exoskeleton provides haptic (force) feedback in response to the subject’s movement. A force sensor located at the hand gripper senses the forces being exerted by “contact” with the virtual environment, and the controller issues commands the exoskeleton in response to the interaction.

Exoskeletons provide significant advantages over other forms of robotics, particularly in rehabilitation applications. Since they surround the whole arm or leg, their motion naturally follows the subject. In addition, they can physically support the limbs during therapy, allowing a more seamless transition between assistive and resistive rehabilitation as a patient progresses.

The Maryland-Georgetown-Army (MGA) Exoskeleton, shown in Fig. 1, is a six degree-of-freedom (DOF) device designed primarily for shoulder rehabilitation. The shoulder assembly consists of three intersecting-axis rotary joints mounted on circular links surrounding the shoulder that replicates a “ball-and-socket” joint. In addition, a scapula joint mounted on the torso is used to replicate the shoulder elevation and depression that occurs as the result of tilting of the scapula joint about the thorax [1]. Other exoskeletons, such as *ARMin II* [9] and *EXARM* [12], also incorporate various degrees of shoulder translation in their designs.

Several rehabilitation exoskeletons built to-date have incorporated virtual reality techniques in their protocol regimen. *L-Exos* built by PERCRO in Italy is a 5-DOF ex-

oskeleton that can cover the full range of motion of the human arm [6]. A reaching task was generated using XVR graphics consisting of several moving spheres that needed to be grasped by subjects. Clinical trials on a group of nine post-stroke subjects resulted in significant improvements in reaching performance [7].



Fig. 1. The MGA Exoskeleton has six degrees of freedom and force/torque sensors mounted on both the upper arm and handle.

The *ARMin*, developed by ETH in Switzerland, is a rehabilitation arm exoskeleton that has 3 DOFs in the shoulder and 1 DOF at the elbow [11]. A game therapy experiment was generated in which a ball was dropped in a virtual environment and the subject had to “catch” the ball. In trials conducted with hemiplegic and spinal cord injury patients, motor functions were improved as noted by decreased reliance on robot support, increased range of motion of the upper limb, and increased motor coordination.

Due to its high torque capacity and control bandwidth, the MGA Exoskeleton can be used for either orthopedic rehabilitation or neuro-rehabilitation via functional training. A flexible control architecture based on composite patterns also allows different combinations of joints to be commanded to achieve multiple objectives. The kinematic design of the exoskeleton is first described in Section II, and then the modular control approach is described in Section III. The development of the graphical interfaces for a virtual wall-painting task are described in Section IV along with preliminary experimental results. Discussion of the results and plans for future work are outlined in Section V.

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II. MECHANICAL DESIGN

The kinematic configuration of the MGA Exoskeleton described in Denavit-Hartenberg (D-H) Notation is shown in Fig. 2 with resultant D-H parameter set given in Table I [5]. The first joint axis is mounted perpendicularly to the back and is used to realize elevation and depression of the shoulder. An orthogonal, intersecting-axis triad is used to generate the 3-axis rotation about the shoulder. The first shoulder axis is mounted at a 30° angle from vertical to rotate the singularity away from the vertical position (alignment of axes 1 & 3). The third shoulder axis intersects the upper arm link at an angle of 45° (rather than being coincident) to increase the range of motion. A single pitch joint drives elbow flexion/extension, and a passive forearm roll joint aft of the gripper allows free forearm supination/pronation through rotation of the handle.

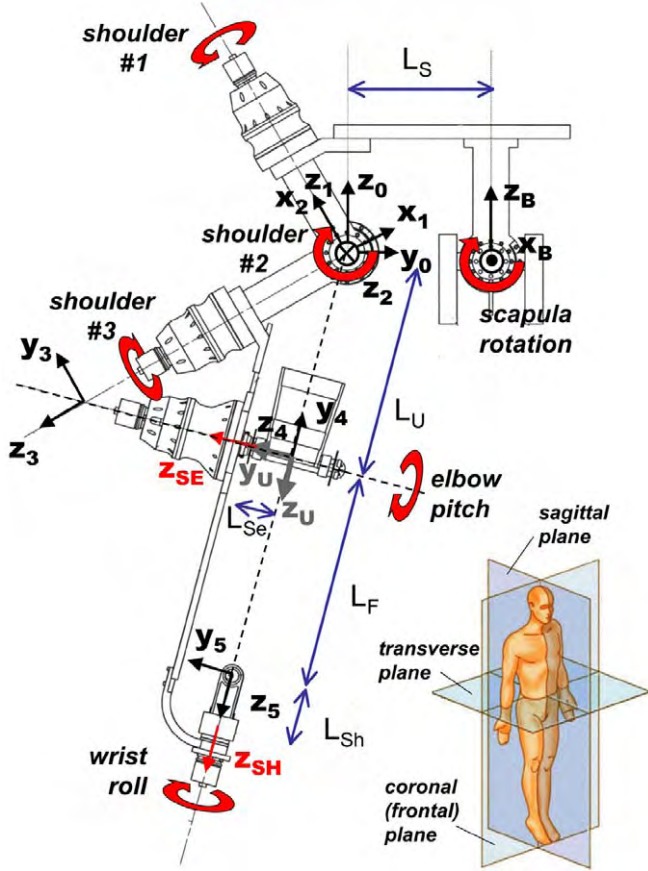


Fig. 2. D-H diagram of MGA Exoskeleton shown in the frontal (coronal) plane. Joint axes are along the z_i -axes, and links L_F , L_U , and L_S have adjustable lengths. The axial directions of the hand and elbow force sensors are represented by z_{SH} and z_{SE} , respectively. The body planes are shown in the inset (<http://en.wikipedia.org/wiki/Image:BodyPlanes.jpg>).

The schematic in Fig. 3 illustrates the resulting articulation of the MGA Exoskeleton. The scapula joint 0 located at B rotates the shoulder S along an arc of radius $\overline{BS}$. Joints 1-3 permit 3-axis rotation about the shoulder glenohumeral joint located at S. Joint 4 generates elbow flexion/extension. Finally, a rotary joint 5 located at the gripper permits passive forearm rotation about line $\overline{EW}$. The joint ranges allow the

TABLE I
D-H PARAMETERS FOR THE MGA EXOSKELETON.

link i	a_{i-1} (cm)	α_{i-1} (deg)	d_i (cm)	$\theta_i^* \text{ home}$ (deg)
1	0	+30	0	+90
2	0	-90	0	-105
3	0	+90	$\sqrt{2}L_U$	-90
4	0	-45	$-L_U$	0
5	0	-90	L_F	0

human arm almost complete freedom of movement within its workspace although shoulder abduction and flexion are somewhat more restricted [4].

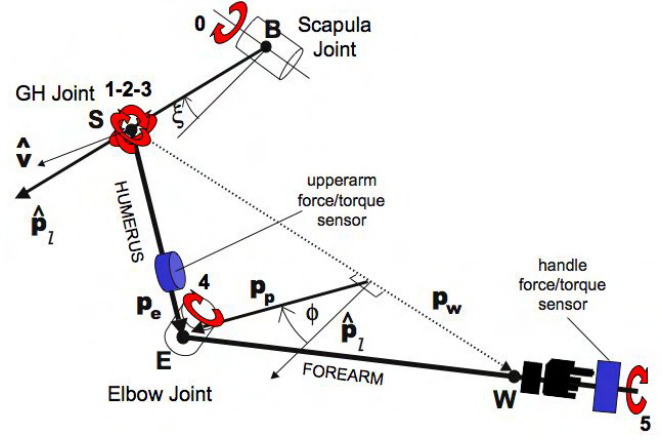


Fig. 3. Schematic representation of MGA Exoskeleton showing four anatomical joint groups and location of the force sensors.

A JR3, Inc. 50M31A force sensor is used to measure forces and torques at the handle, and a JR3 67M25 is mounted between the upper arm cuff and link to determine shoulder torques (see Fig. 4). The sensors are rated for 50 lb (25 lb) in the radial (axial) direction and are equipped with integrated sensor electronics. The six-channel digital output is read by a PCI card inside a PC at 8 KHz.

The linkages and actuator housings are constructed primarily from 6061 aluminum (Al) alloy, with some segments constructed from Al 2024 for increased stiffness. The scapula, upper arm, and forearm links contain passive prismatic joints to accommodate variable subject geometry: $L_S = 14.0 - 25.6$ cm, $L_U = 27.3 - 31.3$ cm, and $L_F = 30.0 - 39.0$ cm. The total mass of the exoskeleton is 11 kg, with the 1 kg actuator modules accounting for nearly half of the weight.

To simplify the forward kinematics, the base frame was chosen to be frame $\{0\}$ rather than frame $\{B\}$ due to the complexity introduced by the 30° skew angle between the z_0 and z_1 axes. Frame $\{B\}$ is then defined as a $-\theta_0$ rotation of the scapula joint about the x_0 -axis from frame $\{0\}$ resulting in the translation ${}^B p_0$ and rotation ${}^B R_0$ relative to the base frame. The transformations between the base, handle, and body frames can then be cascaded to determine the position and orientation of the handle with respect to the body frame as follows:

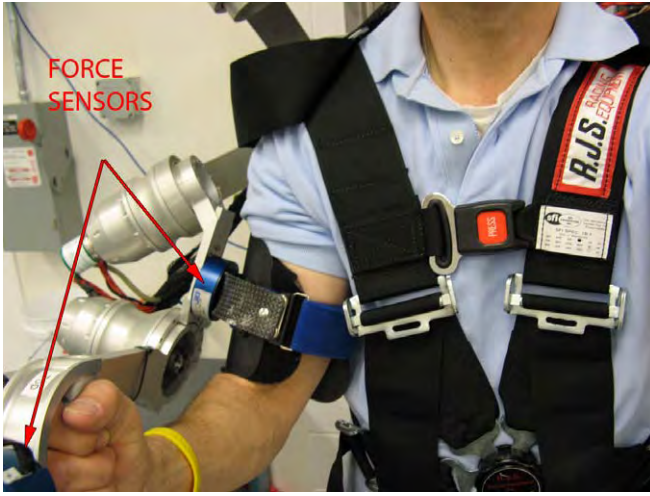


Fig. 4. A close-up of the MGA Exoskeleton showing the (blue) force-sensors mounted on the upper arm and wrist.

$${}^B R_5 = {}^B R_0 {}^0 R_5 \quad (1)$$

$${}^B p_5 = {}^B p_0 + {}^B R_0 {}^0 p_5 \quad (2)$$

The forward kinematics from joint 0 to joint 5, ${}^0 p_5$ and ${}^0 R_5$, are found by first finding the local link position and rotation transforms, ${}^i p_{i+1}$ and ${}^i R_{i+1}$ using the D-H parameters from Table I. These transforms are then cascaded to find the position ${}^0 p_5$ and orientation ${}^0 R_5$ of the handle with respect to the base frame [5].

Exoskeleton motion can still occur when the position of the hand and scapula are held fixed. This “self-motion” represents the ability of the elbow to “orbit” about the shoulder-wrist $\overline{SW}$ shown in Fig. 3. The elbow orbit angle ϕ is defined as the angle that the plane formed by the points S, E, and W makes with the reference plane defined by the reference vector, $\hat{v}$, and the shoulder-wrist vector, p_w [8]. Define the wrist and elbow vectors as $p_w \equiv {}^0 p_5$ and $p_e \equiv {}^0 p_4$, respectively, and let $\hat{v}$ denote an arbitrary fixed unit reference vector. The “elbow orbit angle” is then defined as the angle between p_p and p_ℓ

$$p_p \equiv p_e - \hat{p}_w (\hat{p}_w^T p_e) \quad (3)$$

$$p_\ell \equiv (p_w \times \hat{v}) \times p_w \quad (4)$$

$$\tan \phi = \frac{\hat{p}_w^T (p_\ell \times p_p)}{p_\ell^T p_p} \quad (5)$$

Since the elbow orbit angle is a rather complex function of the arm angles, ϕ is more easily computed by performing the numerical vector operation in (5) and then taking the arctangent of the result.

III. CONTROL SYSTEM

Because the exoskeleton is kinematically redundant with respect to hand position, a second haptic interface is required in addition to the gripper. This additional interface is located at the arm cuff that connects the humerus to the upper arm

link. For tasks that are dominated by hand placement, the arm cuff interface is used to control the torque that produces the arm self-motion. For example, during a reaching task, this interface can be used to enforce proper shoulder abduction, which is often absent in stroke patients [14]. During shoulder exercises, such as shoulder abduction or flexion, the arm cuff becomes the primary haptic interface that controls shoulder rotation [2].

To accommodate multiple haptic interfaces and an extra scapula joint, a “composite” control architecture was developed that is capable of controlling different sets of exoskeleton joints concurrently [3]. For example, in shoulder rotation exercises, the three shoulder glenohumeral (GH) joints are controlled as one group (GH) while the scapula (SC) and elbow (EP) joints are controlled independently. In functional tasks involving whole arm motion, the shoulder and elbow joints are controlled together (XW) because they both determine hand position and elbow orbit, and then the scapula joint (SC) is controlled independently.

Each subcontroller can operate in impedance, admittance, or position mode, which issues either position or torque commands to the joint servos. If motion dominates the dynamic behavior at the haptic interface, then the exoskeleton functions as the impedance device moving in response to the forces exerted by the subject. If the contact forces are dominant at the haptic interface, then the exoskeleton acts as the admittance device and the sensed forces at the handle (or upper arm) are used to drive its motion.

An example of a valid composite control realization for a whole arm task invokes two sub-controllers as shown in Fig. 5: scapula (Sc) position control for joint 0 and wrist translation/elbow orbit control (XW) for joints 1-4. The wrist translation and elbow orbit motion are co-dependent on the four arm joint angles and are either determined by force or position input from the operator. A position controller is used to independently drive the scapula joint as a function of the upper arm elevation. The subcontrollers that were used in the wall-painting experiment are described below.

A. Wrist/Elbow Admittance Module

The admittance controller shown in Fig. 6 is used to convert the sensed contact forces at the handle and elbow orbit torque into desired movements of the exoskeleton. Force signals at the hand are relayed to an admittance model of the virtual environment, which then outputs a desired velocity for the wrist, $\dot{p}_w$. The z-component of the elbow force sensor in f_{S_e} is used to determine the torque, τ_ϕ , exerted about the shoulder-wrist axis, p_w . The elbow orbit torque is calculated by taking the product of the z-component of the force multiplied by the moment arm

$$\tau_\phi \equiv |p_p| f_{S_e} \bullet \hat{z} \quad (6)$$

where p_p is the minimum distance from the elbow to $\overline{SW}$.

The inverse kinematics for the arm joint angles θ_a are found from ${}^0 p_5$ and ϕ using the extended Jacobian approach [13]. Because of the complex dependence of the

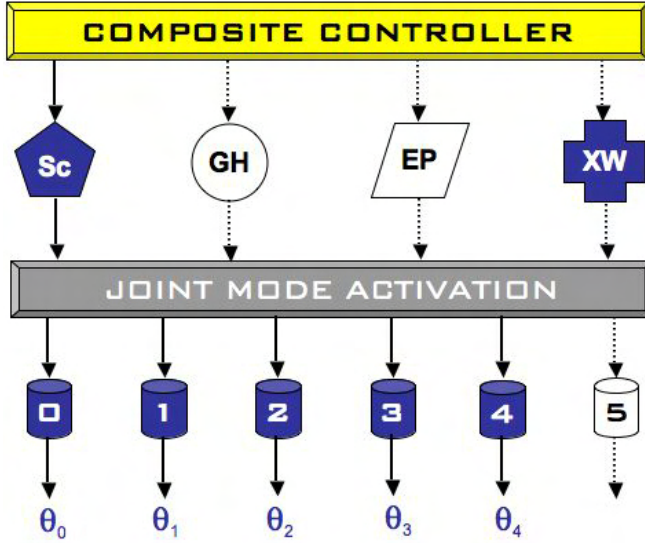


Fig. 5. A composite control realization for a whole arm task, where the Sc subcontroller outputs a scapula position command and the XW admittance subcontroller outputs shoulder/elbow joint position commands.

wrist position and, in particular, the elbow orbit angle on the joint angles, an analytical solution for the exoskeleton inverse kinematics is not realizable. Thus, a Newton-Raphson iterative procedure is used to determine the change in joint angles as a function of the desired change in wrist position and elbow orbit angle.

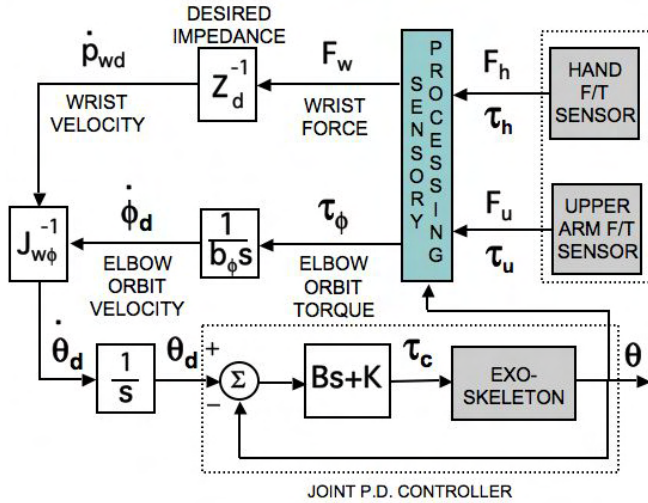


Fig. 6. The admittance controller utilizes force inputs from the force sensors mounted on the upper arm and handle to compute the desired wrist velocity and elbow orbit angular rate, which are then input to the inverse kinematics to determine the exoskeleton joint rates.

B. Scapula PD Module

Maintaining the center of rotation of the exoskeleton and human shoulder joints is important because misalignment stresses can cause discomfort, pain, and possibly even damage to the shoulder under repetitive motion [11]. Thus the exoskeleton's scapula joint is commanded to follow a biomechanical model of the motion of the human's glenohumeral

(GH) joint as the upper arm elevates. Data of GH motion from [10] was used to generate curve fits for the GH vertical displacement Δy as a function of the humerus elevation ξ , where $\Delta y = 0$ represents the shoulder elevation when the arm is extended horizontally at 90° [4]. Since the z-axis of the upper arm frame $\{U\}$ is directed along the humerus, the humerus elevation can be obtained from the dot product of the z-axis of frame $\{U\}$ with the z-axis (azimuth) of the body frame $\{B\}$, i.e. the (3,3) element of ${}^B R_U$

$$\xi = 180^\circ - \cos^{-1}({}^B R_{U,3,3}) \quad (7)$$

where $\xi = 0^\circ$ when the humerus is vertical against the side of the trunk. Thus the desired scapula angle is obtained from

$$\theta_0 = \tan^{-1}(\Delta y/L_S) \quad (8)$$

where the scapula link length L_S is adjusted to be the length of the clavicle (≈ 15 cm for the average adult male [4]).

IV. WALL PAINTING EXPERIMENT

An architectural overview of the control system is shown in Figure 7. The control station runs a Mac OS X operating system and implements a set of graphical interfaces written in Trolltech Qt 4 to select protocols, initiate/terminate operation, and monitor subject data. The control station communicates over the Internet with the robot control computer, which is used to execute the main control loop and safety monitoring system. The robot control computer runs a TimeSys6 Linux real-time operating system at 125 Hz to ensure safety deadlines. A dual channel PCI card in the robot control computer processes strain gauge signals from the JR3 force sensors at 8 KHz and sends the resulting force data to the arm controllers.

Each joint is driven by a Kollmorgen brushless DC motor (RBE series) and harmonic drive transmission from HD Systems (CSF/CSD series). Communication and power are routed through an umbilical to a Galil DMC18x6 6-Axis motion control card running at 1000 Hz and B30A8 brushless servo amplifiers from Advanced Motion Control, Inc. Motor position is determined using a Numerik Jena 1800-line optical incremental encoder mounted to the motor shaft. Absolute 12-bit optical encoders from Gurley Precision Instruments (Model A37B) are mounted at the output of the transmission to determine absolute position on start up and to monitor the incremental encoders.

Qt was used to generate the virtual wall graphics seen in Fig. 8. An icon of a paintbrush is drawn on a plain background based on the Cartesian pose of the exoskeleton handle. Movement of the exoskeleton handle causes movement of the paintbrush in the graphical interface. When the roller makes contact with the wall, a bright green swath is painted along the surface. A bar graph is superposed on the wall to indicate the level of force to the user who attempts to keep it within a specified range.

The graphical user interface shown in Fig. 9 allows the clinician to input parameters for the wall-painting task.

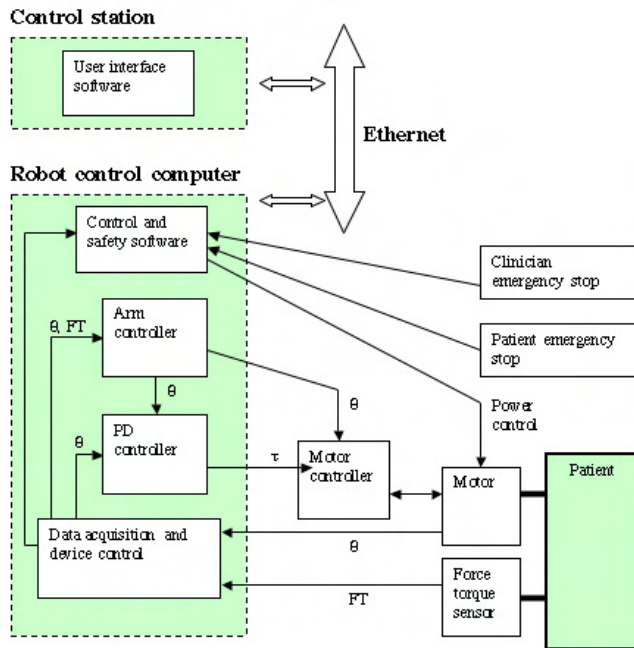


Fig. 7. Exoskeleton control system architecture.

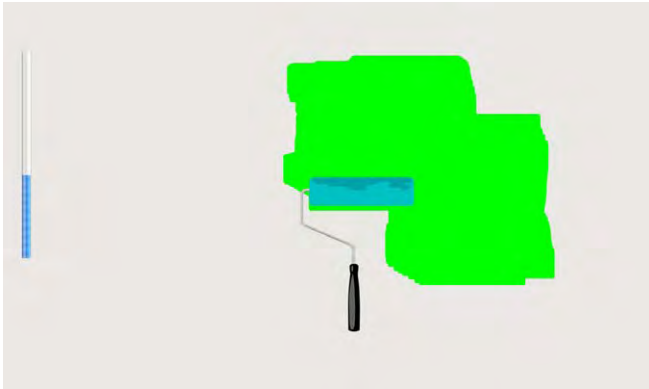


Fig. 8. Wall painting graphics developed using Qt 4.

Graphical icons are used to navigate the input space, allowing a more natural selection of the task parameters. The plane of the wall is chosen using radio buttons (coronal, transverse, or sagittal), and the wall distance is input using the boxes to the left. Wall, ceiling, and floor boundaries are chosen to restrict the workspace. Finally, the wall stiffness and damping parameters are chosen using sliders and buttons, or they can be input numerically in the boxes provided.

In the experiments, the stiffness of the wall was chosen to be 1500 N/m, and the damping was $B=1500$ N/m/s normal to the wall. In the directions tangent to the wall, stiffness was zero and damping was 100 N/m/s. The elbow orbit damping was chosen to be 50 N-m/rad/s. Since zero impedance is not realizable with an admittance controller, a finite damping value of 100 N/m/s was used in all directions in freespace.

A video snapshot of the experimental setup is shown in Fig. 10. The virtual wall is located in the Coronal plane at a distance of 0.4 m from the intersection of the body plane

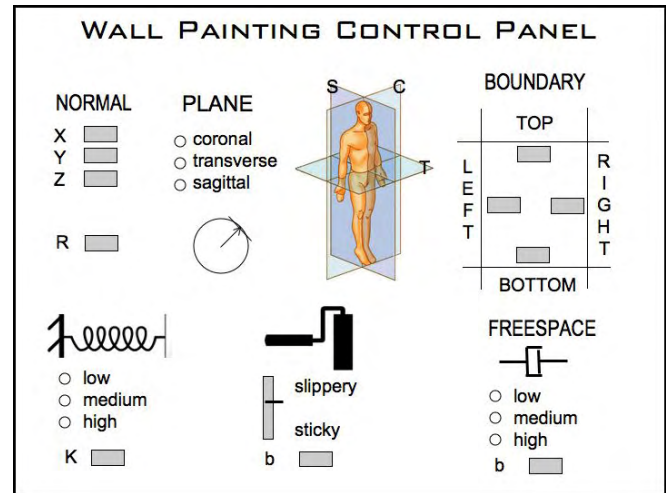


Fig. 9. Control GUI being developed for the wall-painting task allows selection of wall position, boundaries, and stiffness as well as viscosity of the roller brush on the wall surface.

axes. The subject starts with their hand a few centimeters in front of the wall and then moves forward until contact is made. The subject was told to hold a constant force on the surface, but the force level is not currently displayed. The force reached a peak of about 60 N for a 3 cm “deflection” of the wall surface as seen in Fig. 11.

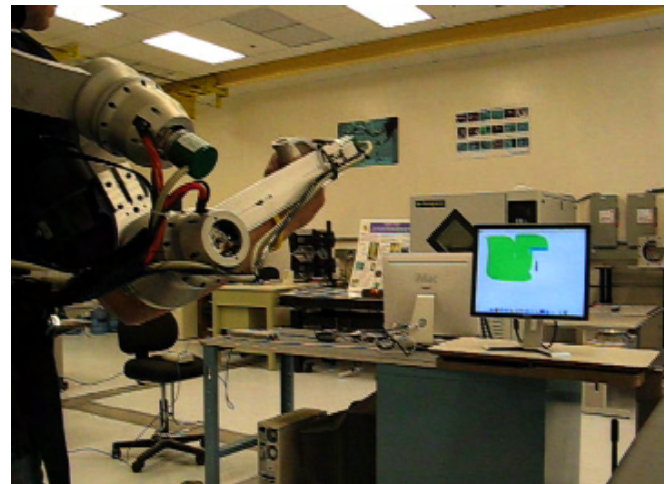


Fig. 10. Video capture of subject performing wall-painting task.

A 3D rendering of the hand path is shown in Fig. 12, where the color indicates the level of force exerted at each point. As can be seen, the force increase greatly past 0.4 m, which is the location of the wall. However, viscous damping also results in resistance even when the brush is not in contact with the virtual wall shown in Fig. 10. The wall stiffness was limited to about 2000 N/m by stability considerations in the admittance controller and requires nonzero damping impedances in all directions. This causes an unnatural simulation when the brush is lifted off the wall and moved to another location.

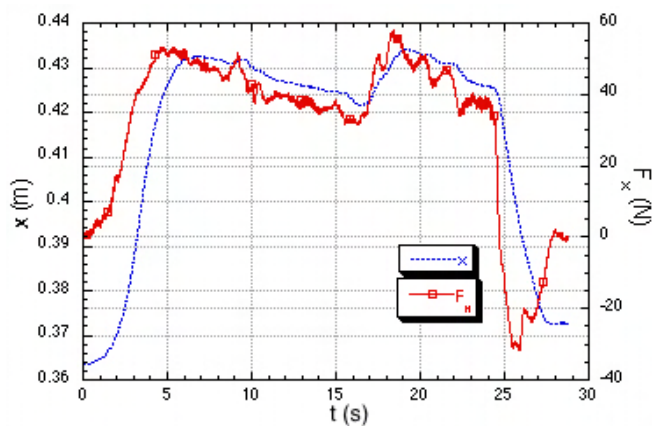


Fig. 11. Handle position and contact force normal to wall.

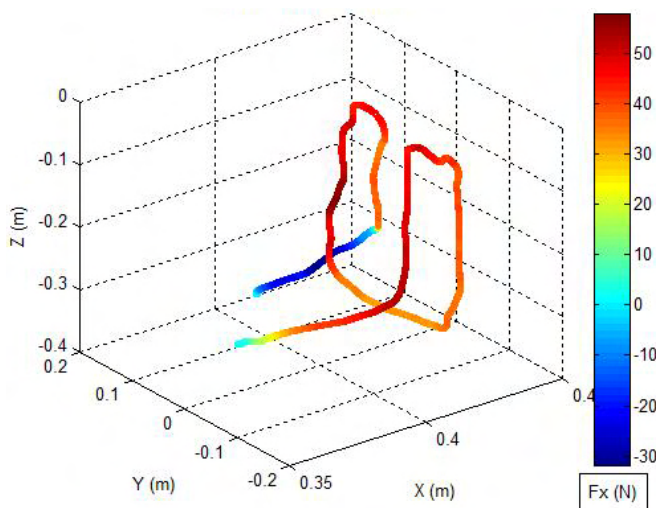


Fig. 12. Cartesian path of handle shown in 3D perspective. The color of the line indicates the level of force exerted normal to the wall.

V. CONCLUSION

The MGA Exoskeleton was used in conjunction with a Qt-generated virtual environment to create a simple wall-painting virtual task for rehabilitation. This task will allow the clinician to specify a desired range of forces to be applied to the virtual wall by the roller brush and cause the patient to abduct the shoulder in order to accomplish the task. The controller was able to replicate the desired wall stiffness and viscosity along the wall surface during the task.

An impedance controller is being developed that will allow low impedance simulations of the same task and zero impedance in freespace. Implementation of the impedance controller will require gravity and friction compensation to cancel out the dominant (non-inertial) dynamics of the exoskeleton at low accelerations. The link masses and joint frictions have been characterized for the compensation and are now being tested with the controller.

ACKNOWLEDGMENTS

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sored by the U.S. Army Telemedicine and Advanced Technology Research Center under #W81XWH-08-2-0010.

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8.4 Flyer: IEEE Spring 2008 Symposium, "Technology for the Golden Years"



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In collaboration with chapters of the following IEEE societies:

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When:

Saturday, May 10, 2008
9 a.m. – 4 p.m.

Where:

University of Maryland
Jeong H. Kim Engineering Building
1st Floor Lecture Hall #1110
College Park, Maryland 20742

Register online:

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Mail deadline: May 1, 2008
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hartman_k@computer.org
703 623 1432 (voice)

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Includes breakfast and lunch.

Affiliation	Before 5/6/08	After 5/6/08
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SPRING SYMPOSIUM

Technology for the Golden Years

Saturday, May 10, 2008

The IEEE Washington and Northern Virginia Sections present the **2008 Spring Symposium on "Technology for the Golden Years: Leading an Independent Life in the 21st Century"** at the University of Maryland College Park campus on Saturday, May 10 from 9:00 a.m. to 4:00 p.m. The symposium is open to both professionals and students.

The symposium will explore the use of robotics and sensor technologies to help the elderly live independently. Speakers from industry, academia and research provide their research and application in design and implementation, using robotics and sensors aiding individuals to lead productive and independent lives. Speakers will address:

- Robotic Technology to Assist Elderly
- Personal Automobility
- Next Generation of Sensors for remote Monitoring & Alerting
- Product Development Challenges
- Rehabilitation System

Join us for an informative day in the use and application of cutting edge technology for disabled and elder care.

ABOUT THE SPEAKERS

Dr. Henrik Christensen, KUKA Chair of Robotics and Intelligent Machines at the Georgia Institute of Technology's College of Computing and Interactive Computing, provides an overview of current methods and how today's research will lead to sustainable technologies that allow people to maintain their autonomy as they grow old. He presents a variety of examples from basic assistance to the complex, and describes a number of challenges for the future.

Ms. Cindy Crump is founder and CEO of AFrame Digital, Inc. of Falls Church, Virginia, a research-based health technology company developing innovative wireless remote health monitoring applications to address the needs of elders and other at-risk populations. She explores the ways that continuous 24/7 remote monitoring of patients in the home, outpatient rehabilitation and institutional long term care will fill the gaps between office visits and provide a true safety net for individuals with chronic issues.

Dr. John Spletzer is an Assistant Professor of Computer Science and Engineering at Lehigh University. Dr. Spletzer discusses the research and development of the Automated Transport and Retrieval System (ATRS), a technology-based solution for drivers in wheelchairs. ATRS integrates robotics and automation technologies into a traditional automobile without making permanent changes to the vehicle, thus eliminating the need for an attendant or costly van conversion.

Dr. Satyandra K. Gupta, an Associate Professor in the Mechanical Engineering Department and the Institute for Systems Research at the University of Maryland, will present the challenges faced by current designers in understanding the implications of their design decisions on the lives of people with disabilities as well as developing product platforms to offer low cost solutions. In addition, he will discuss why the needs of people with disabilities should be emphasized in the undergraduate engineering design curriculum.

Dr. Craig Carignan, a Research Associate Professor at Georgetown University's Imaging Science and Information Systems Center, will present and demonstrate his current research involving a robotic arm exoskeleton rehabilitation system. Treatments for common pathologies such as rotator cuff tear or impingement range from exercise rehabilitation to surgery and, in extreme cases, to shoulder joint replacement.

**8.5 Presentation: "A Robotic Arm Exoskeleton for Shoulder Rehabilitation",
IEEE Spring Symposium, May 2008**

LEADING AND INDEPENDENT LIFE IN THE 21ST CENTURY

"A Robotic Arm Exoskeleton for Shoulder Rehabilitation"

Craig Carignan, Jonathan Tang, Emmanuel Wilson
Georgetown University,
Dept. of Radiology/ISIS Center

Stephen Roderick, Michael Naylor, Michael Liska
University of Maryland
Space Systems Laboratory

IEEE Wash DC/NOVA Symposium:
Technology for the Golden Years
College Park, Maryland, May 10, 2008



fit

Safeguard Your Shoulders

It's Lorraine's but not her shoulder's fault. For most people, the pain when you get back into the gym is going to be coming from your shoulder. It's not your shoulder's fault. It's your weight training. The shoulder is a very vulnerable joint. It's the only joint in the body that has no ligaments to hold it together. It's the only joint in the body that has no cartilage to cushion it. It's the only joint in the body that has no blood supply. It's the only joint in the body that has no nerve supply. It's the only joint in the body that has no pain receptors. It's the only joint in the body that has no defense. It's the only joint in the body that has no protection. It's the only joint in the body that has no support. It's the only joint in the body that has no strength. It's the only joint in the body that has no power. It's the only joint in the body that has no endurance. It's the only joint in the body that has no stamina. It's the only joint in the body that has no resilience. It's the only joint in the body that has no flexibility. It's the only joint in the body that has no mobility. It's the only joint in the body that has no range of motion. It's the only joint in the body that has no stability. It's the only joint in the body that has no balance. It's the only joint in the body that has no coordination. It's the only joint in the body that has no control. It's the only joint in the body that has no precision. It's the only joint in the body that has no accuracy. It's the only joint in the body that has no consistency. It's the only joint in the body that has no reliability. It's the only joint in the body that has no dependability. It's the only joint in the body that has no predictability. It's the only joint in the body that has no measurability. It's the only joint in the body that has no quantifiability. It's the only joint in the body that has no calculability. It's the only joint in the body that has no estimability. It's the only joint in the body that has no assessability. It's the only joint in the body that has no evaluability.

EQUIPMENT FAILURE?

40
70
80
90
100

oh, oh ... trouble ahead!

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The Shoulder - Mobility at a Price!

In the U.S., 15 million people seek medical care for the shoulder each year making it the #1 Injured Joint in the upper extremity!



"It's ironic that when we start 'taking care of ourselves' by working out, we often cause injury to the shoulder."
- Brian Schiff, PT, CSCS

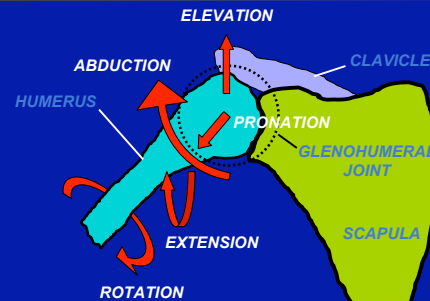
INJURY LIST:
rotator cuff tear,
dislocated shoulder,
tendonitis,
shoulder separation,
capsule tear,
frozen shoulder,
bursitis.



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Shoulder Motion



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Difficulties of Manual Therapy

- ❑ Labor intensive
- ❑ Resistance training does not match our strength profile
- ❑ Hard to maintain form and produce correct motion
- ❑ Little or no quantitative feedback on progress
- ❑ Functional training is difficult



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The Robotic Advantage

- Don't get tired of repetitive motions
- Produce consistent force inputs for physical therapy
- Provide quantitative feedback for monitoring progress
- Can function as force-feedback devices for "functional" therapy



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Gait Rehabilitation



Lokomat Exoskeleton, Hocoma, Switzerland (2005)



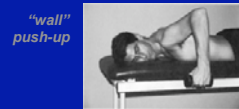
ZeroG OverGround Body Weight Support System, National Rehabilitation Hospital (2008)

Arm Rehabilitation

ISOLATERAL



shoulder abduction



"wall" push-up

- simple, isolated joint motion
- emphasis on maximum load
- builds muscle strength

FUNCTIONAL



PNF D1 Pattern



ADL Task

- complex motion mimics task
- emphasis on proper movement
- builds coordination & stability

Exoskeleton for Shoulder Rehab?



Isolation Therapy



Functional Rehabilitation

Exoskeleton Classes

ORTHOTIC

REHABILITATION

AUGMENTATION



SUPPORT LIMB LOAD

supports limb and small loads (portable)



(MIT Elbow, Myomo, Inc.)

MAXIMUM HUMAN STRENGTH

can resist human strength (portable or non-portable)



(ARMin, ETH Zurich)

superhuman strength for carrying heavy loads (portable, "driveable")



(REX, Sarcos, Inc.)

Patient Movement Ratings

Rating	Strength	Description
0	0%	cannot contract muscle
1	10% (trace)	trace of muscle contraction but cannot move limb
2	25% (poor)	can perform ROM* in a gravity eliminated position
3	50% (fair)	can perform ROM against gravity but no external resistance
4	75% (good)	can perform ROM against gravity and with moderate resistance
5	100% (normal)	can perform ROM against gravity and full resistance

*ROM = Range of Motion

Assistive Exoskeletons (Orthoses)



MIT NeuroRobotic Elbow, Myomo, Inc.

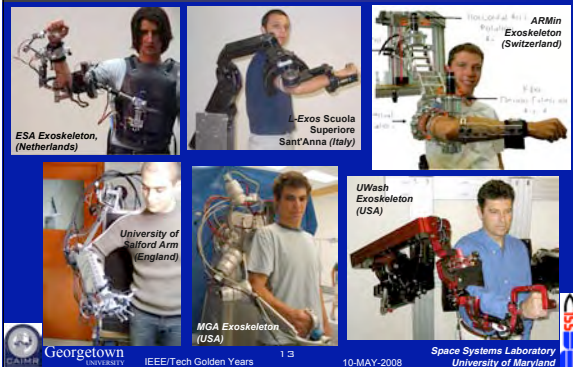


ReWalk, Argo Medical Technologies, Israel



HAL 5 exoskeleton, Cyberdyne, Japan.

Rehabilitation Exoskeletons



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Augmentation Exoskeletons



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Exoskeleton Advantages

- ❑ Surround the whole arm or leg rather than just distal end
- ❑ Can progress from an assistive device to a resistive trainer
- ❑ Large range of motion and natural feel
- ❑ Forces/torques can be applied at multiple points of contact
- ❑ Specific joints/muscle groups can be targeted for therapy

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Human-Robot Interaction

- ❑ Exercise therapy can require the application of large forces over large range of motion
- ❑ There are multiple points of contact between the human and exoskeleton
- ❑ Exercise protocols may require simultaneous operation of multiple controllers
- ❑ Exoskeletons are at the extreme end of safety-critical robotic systems



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Current Robot Safety Standards

STAY OUT OF THE ROBOT'S WORKSPACE!!!

-ANSI/RIA R15.06



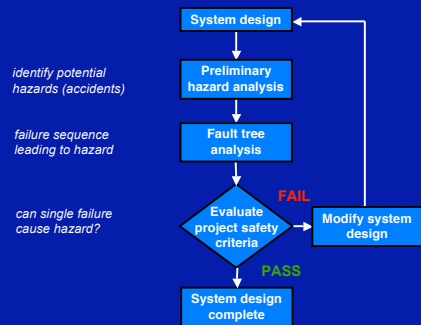
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Why Computer-Based Safety?

- ❑ While the hardware design can enhance safety, it cannot ensure it
- ❑ Computer monitoring is necessary to reliably determine excess velocities and forces
- ❑ Events happen too quickly to rely on a human operator to intervene
- ❑ The **operator** is also the **patient!**

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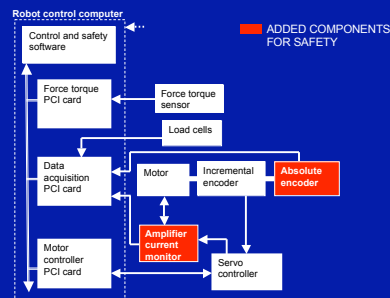
Safety Design Process



Exoskeleton Safety Criteria

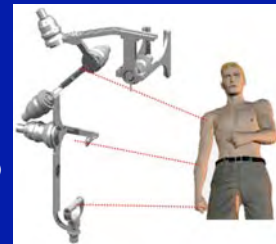
- The system will be able to detect **any single** failure event and autonomously enter a safe state
- Safe state is either:
 - actively holding position and not exerting any force on the patient
 - complete power-down of the exoskeleton
- Design is based on approach certified by NASA for a robot designated to fly on the Space Shuttle

Added Safety Components



MGA Exoskeleton (MGAXOS)

- Range of Motion
 - scapula elevation ($0^\circ/30^\circ$)
 - shoulder flex/ext ($147^\circ/46^\circ$)
 - shoulder abd/add ($105^\circ/75^\circ$)
 - shoulder rotation ($105^\circ/75^\circ$)
 - elbow flex/ext ($142^\circ/0^\circ$)
 - forearm pro/sup ($180^\circ/180^\circ$)
- Torque Output
 - 137 N-m scapula elevation
 - 137 N-m shoulder rotation (x3)
 - 69 N-m elbow flexion
 - 0 N-m forearm supination
- Link Adjustments
 - clavicle (19.5-26.8 cm)
 - upper arm (27.2-31.2 cm)
 - forearm (23.0-32.0 cm)

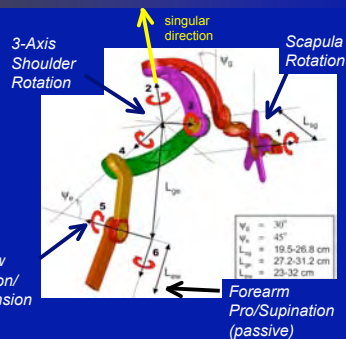


Maryland-Georgetown-Army Exoskeleton (MGAXOS)

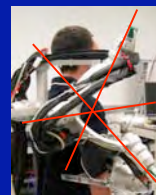
Kinematic Design

SHOULDER:

- 3 Orthogonal axes give full 3-DOF rotation
- 1st axis tilted to avoid gimbal lock for arm down



Key Kinematic Features



3-Axis Shoulder (GH Joint)



Shoulder Elevation (Scapula Joint)



Adjustable Arm Geometry (3 passive links)

Shoulder Design

GOALS:

- maximize rotational workspace
- minimize impact of singularity

Prototype I



Prototype II



would have been
Prototype III ...



Passive MB Exoskeleton
(Wright-Patterson AFB)



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IEEE/Tech Golden Years

25

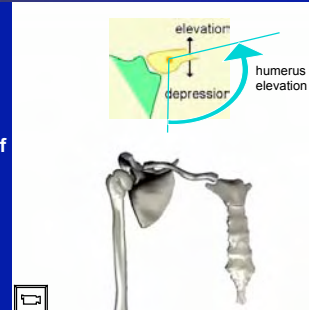
10-MAY-2008

Space Systems Laboratory
University of Maryland

Scapula-Humeral Rhythm

Refers to the elevation of the shoulder glenohumeral joint (GH) that occurs as the humerus (upper arm) rises

- Caused by rotation of the scapula for elevations below 90°
- GH joint moves on surface of sphere with clavicle radius ~ 15 cm



(Animation courtesy of Tobias Nef and Rob Riener, ETH Zurich)



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University of Maryland

Scapula Rotation Video



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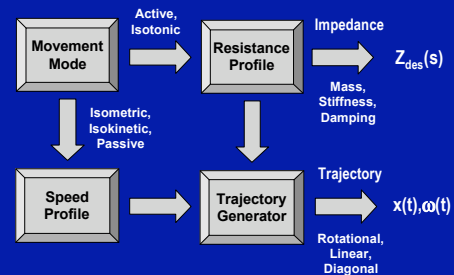
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University of Maryland

Exercise Decomposition



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10-MAY-2008

Space Systems Laboratory
University of Maryland

Movement Modes

MOVEMENT MODE	MUSCLE GRADE	PATIENT ROLE	THERAPIST ROLE
Passive	0, 1	no effort	move limb
Active	2, 3	move limb	no force applied
Isometric	4, 5	maximum effort	immobile
Isokinetic	4, 5	maximum effort	apply constant velocity
Isotonic	5	move load	apply constant load

DEFINITIONS:

Isotonic - Subject moves against constant resistance (is lifting a set weight); this can result in either a concentric (shortening) or eccentric (lengthening) muscle contraction

Isometric - machine is static allowing isometric strength to be tested in any given configuration

Isokinetic - machine produces velocity-controlled active motion; subject develops resistance only if their effort meets or exceeds the velocity of the device



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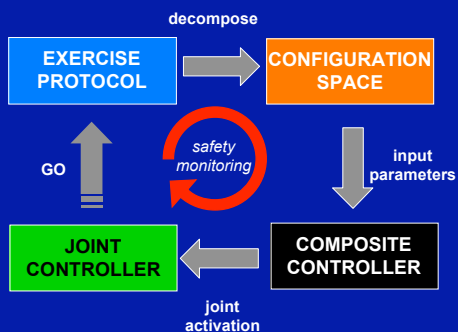
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University of Maryland

Control Activation Cycle



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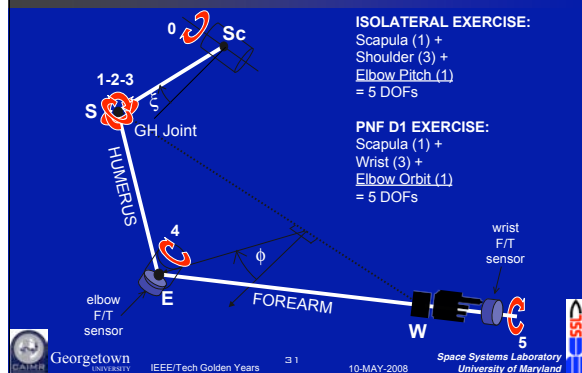
IEEE/Tech Golden Years

30

10-MAY-2008

Space Systems Laboratory
University of Maryland

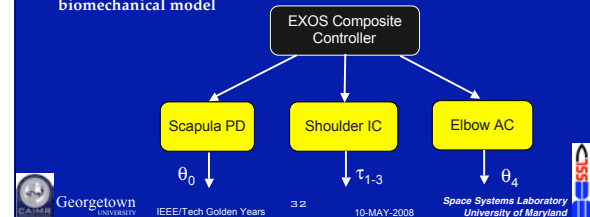
Configuration Space



Composite Control

EXAMPLE: ISOLATERAL

- Desired shoulder rotation axis/impedance selected
- Elbow flexion is free (user force-accommodation)
- Scapula rotation governed by biomechanical model



Example Isolateral Exercises

torso frame



humerus frame



Example Functional Training

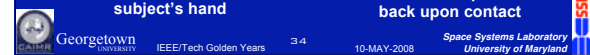
Virtual Wall placed in front of subject



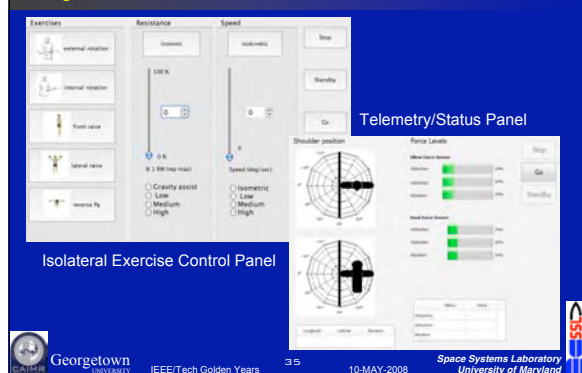
Paint roller tracks subject's hand



Exoskeleton pushes back upon contact



Operator Interfaces



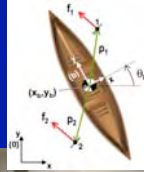
Future Work

- Pilot testing of MGAXOS for use in a clinical setting for initial intervention
- Spinoff a hybrid-powered prototype that is wearable and can be used as an assistive (orthotic) or resistive (rehabilitation) device
- Enhance functional training for wearable prototype using advanced VR graphics (stereovision, etc.)
- Interactive rehabilitation over the internet between patient/doctor



Tele-Rehab/Home Therapy

- Robots enable force-feedback between patient and therapist over the Internet
- Can remotely assess patient's strength, range of motion, speed, spasticity, etc.)
- Can perform computer-generated cooperative tasks over the Internet



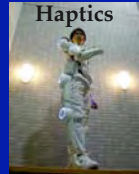
Evolution or Revolution?

Holography



3D MOTION GRAPHICS

+



HAL-5 BODY SUIT



Gimme Holodecks!

The Rise of the Body Bots

Exoskeletons are strutting out of the lab—and they are carrying their creators with them ...

—Erico Guizzo and Harry Goldstein
<http://www.spectrum.ieee.org/oct05/19/011>



QUESTIONS???



ACKNOWLEDGEMENT: This research was sponsored by the U.S. Army Telemedicine and Advanced Research Center.

8.6 Newsletter: IEEE National Capital Area Scanner, vol. 8, no. 4, "Assistive Technologies for Elderly, Disabled Examined at Spring Symposium", July-August 2008

Assistive Technologies for Elderly, Disabled Examined at Spring Symposium

By Jeff Poston, Debi Siering & Tom Starai

On a cool spring Saturday morning, Washington and Northern Virginia section members, guests and speakers convened on the University of Maryland College Park campus in the Jeong Kim Engineering Building lecture hall to hear how robotics and sensors will provide services in the 21st century. Speakers at the May 10 "Technology for the Golden Years" Spring Symposium came from the greater Washington area as well as Georgia and Pennsylvania.

After a continental breakfast, Dr. Henrik Christensen from the Georgia Institute of Technology opened the symposium by discussing the use of robots in everyday life for practical tasks such as cleaning floors and preparing meals. He also described how toys may be designed in the form of animals, such as a seal, in order to quickly gain acceptance in the home. He noted that studies are underway on how family members interact and even bond with robots, as well as how robots impact a family's daily routine.



Robotic Rehabilitation—Dr. Carignan places his arm in the exoskeleton system to demonstrate its operation. (Photo by Michael Pearce)

Dr. John Spletzer from Lehigh University presented his research along with a video on the development of his Automated Transport and Retrieval System (ATRS). The system is a wheelchair that docks itself to a vehicle, thus enabling a person in a wheelchair to enter and exit a vehicle without assistance. He discussed the hurdles

that his team overcame during preliminary testing of the ATRS. Next, a disabled veteran has volunteered to test the ATRS without manual intervention.

During the lunch break, four students from the University of Maryland's Institute of Systems Research (ISR), Kevin Galloway, Philip Twu, Matteo Mischianti and Ermin Wei, entertained the audience with Cricket, a four-wheel pioneer robot is able to navigate and avoid objects autonomously. The students are investigating using Cricket to assist a disabled or elderly person in everyday tasks.

After lunch, Cindy Crump from AFrame Digital in Virginia presented monitors for a resident safety net. A wristwatch device worn by the individual will sense impact of injury and patient status. Gate stability research included microprocessors and a tri-axial accelerometer to identify the point in which someone is about to fall. She noted that the entertainment industry is the market driver for the virtual environment.

Dr. Satyandra Gupta provided insight on

the challenges faced by ISR at the University of Maryland. His discussion included how to approach designs to ultimately develop usable platforms for individuals with disability that provide low cost solutions.

Dr. Craig Carignan is a research professor both at Georgetown and the University of Maryland. He briefed the audience on an exoskeleton rehabilitation system that his team is working on and how it could help someone with a shoulder injury rebuild a rotator cuff tear. Dr. Carignan then invited everyone to walk down the hall to a lab where he demonstrated the device.

Afterwards the speakers and volunteers were recognized for their personal contributions and altruism that was exemplified in making an inexpensive local conference such an enjoyable success.

Special thanks go to our volunteers: Pablo Salazar, Khai Lai, Jonathan Hoang, Angel Berrocal, Renato Cabrera, Derek Wood, Professor Uche Abanulo, Ann Sauberman, Harry Sauberman, Elsie Grant and Kerry Hartman.

8.7 Presentation: "Robotic Exoskeletons for Strength Training and Rehabilitation", NSCA PA State Strength and Condition Clinic, June 2008

"Robotic Exoskeletons for Strength Training & Rehabilitation"

Craig Carignan, Sc.D., PT-NCSF

Res. Assoc., Georgetown University
Adj. Prof. University of Maryland
crc32@georgetown.edu

<http://www.isis.georgetown.edu/caimr/>

National Strength & Conditioning Association
Pennsylvania State Strength & Conditioning Clinic
Juniata College, Huntingdon, PA, June 27/28, 2008



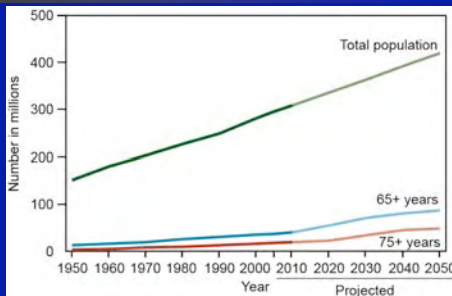
oh, oh ... trouble ahead!

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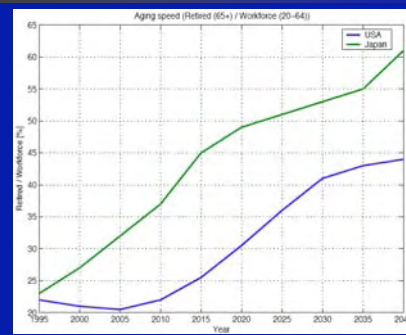
Georgetown University

Our Aging Population



Sources: Centers for Disease Control and Prevention, National Center for Health Statistics, Health, United States, 2007, Figure 1. Data from the U.S. Census Bureau.

Things could be worse ...



QUESTION:
Can you name a European country in almost as bad shape as Japan?

[WorldBank]

Surging Therapist Demand

- Increased number of individuals with disabilities
- Baby-boomers entering prime age for heart attacks and strokes
- Advanced technologies to save larger proportion of babies with birth defects
- Increased interest in health promotion



Source: US Occupational Outlook Handbook

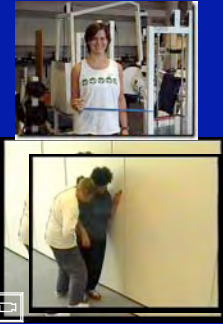
Scary Statistic: The average age of a physical therapist has increased from 36 to 41 in the last decade! [APTA]

Impact on Trainers

- An increasing number of your clients and/or athletes will have some type of injury
- You – and NOT a therapist – will be their primary source of therapy
- You will need to know more about rehabilitation

Difficulties of Manual Training

- Resistance does not match strength profile
- Hard to maintain correct form over range of motion
- Little or no quantitative feedback on progress
- Functional training is difficult
- Therapy can be labor-intensive
- Spotter needed for safety



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How Can Robotics Help?

- Produce consistent force inputs for training and physical therapy
- Individually tailor resistance profiles for different subjects
- Provide quantitative feedback for monitoring progress
- Can be used for force-feedback during functional training
- Computer monitoring for safety

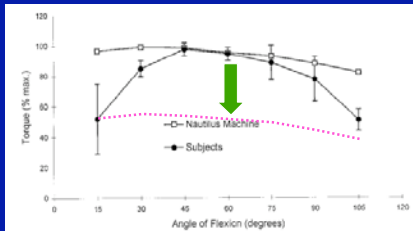
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Strength Profile/Machine

Machine resistive torque versus human torque capability at 45°/sec (normalized to percent of maximum).



machine weight must be lowered to accommodate weakest point in range of motion

L. Cabell & C. Zebas, "Resistive Torque Validation of the Nautilus Multi-Biceps Machine", J. of Strength & Conditioning, 1999: 13(1).

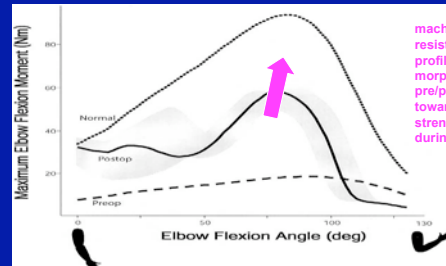
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Abnormal Strength Profiles

Strength profile mismatch due to surgical intervention



machine resistance profile could be morphed from pre/post-op toward normal strength profile during rehab

K. Saul, W. Murray, V. Hentz, S. Delp, "Biomechanics of the Steindler Flexorplasty Surgery: A Computer Simulation Study", The Journal of Hand Surgery, Nov. 2003: 28A(6).

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Robotic Platforms

Weight Machines

1D



Planar Robot



Exoskeletons 3D

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Smart Exercise Machines



Keiser Arm Curl 250

replaced pneumatic cylinder with leadscrew actuator

- SmartMotor Controller
- UltraMotion Leadscrew
- Sensotec Load Cell

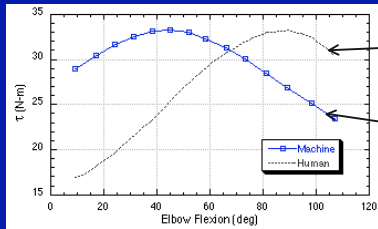


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Arm Curl Machine Strength



Strength profile for stock machine does not match human strength profile!

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Motorized Arm Curling



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Body Weight Support System



For gait training over uneven surfaces.



ZeroG OverGround Body Weight Support System (National Rehabilitation Hospital)

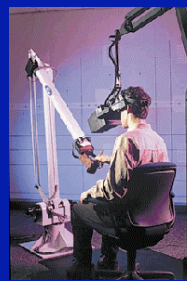
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External versus Wearable

External



Ford Motor Co. Driving Simulator

Wearable



EXOS Arm Exoskeleton (1993)

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Exoskeleton Advantages

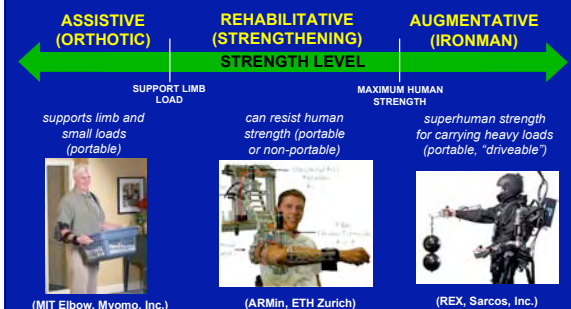
- Surround the whole arm or leg rather than just the hand or foot
- Large range of motion and moves with subject
- Forces/torques can be applied at multiple points of contact
- Specific joints/muscle groups can be targeted for therapy

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Exoskeleton Classes



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Assistive Exoskeletons



MIT NeuroRobotic Elbow,
Myomo, Inc.



ReWalk, Argo Medical
Technologies, Israel



HAL 5 exoskeleton,
Cyberdyne, Japan.

<http://youtube.com/watch?v=VSP46fWvxJ4>

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Augmentation Exoskeletons



BLEEX, UC Berkeley



REX, Sarcos/Raytheon, Inc.

<http://youtube.com/watch?v=IYwd2C3XVik>

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Rehab Leg Exoskeletons



Lokomat Leg Orthosis,
Hocoma, Switzerland (2005)



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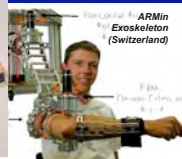
Rehab Arm Exoskeletons



UWash
Exoskeleton
(USA)



L'Exos Scuola
Superiore
Sant'Anna (Italy)



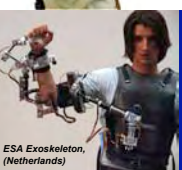
UCLA's ARMin
Exoskeleton
(Switzerland)



University of
Salford Arm
(England)



MGA Exoskeleton
(USA)



ESA Exoskeleton,
(Netherlands)

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Exoskeleton Challenges

- ❑ Exercise therapy can require the application of large forces over large range of motion
- ❑ There are multiple points of contact between the human and exoskeleton
- ❑ Exercise protocols may require simultaneous operation of multiple controllers
- ❑ Exoskeletons are at the extreme end of safety-critical robotic systems



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Current Robot Safety Standards

**STAY OUT OF THE ROBOT'S
WORKSPACE!!!**

-ANSI/RIA R15.06

WHOA ...
you talkin'
to me?



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Shoulder – Mobility at a Price!

In the U.S., 15 million people seek medical care for the shoulder each year making it the #1 injury in the upper extremity!



"It's ironic that when we start 'taking care of ourselves' by working out, we often cause injury to the shoulder."
– Brian Schiff, PT, CSCS

INJURY LIST:
rotator cuff tear,
dislocated shoulder,
tendonitis,
shoulder separation,
capsule tear,
frozen shoulder,
bursitis,

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Shoulder Exercises

ISOLATERAL



shoulder abduction

"wall" push-up



- simple, isolated joint motion
- emphasis on maximum load
- builds muscle strength

FUNCTIONAL

PNF D1 Pattern



ADL Task



- complex motion mimics task
- emphasis on proper movement
- builds coordination & stability

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Robotic Shoulder Therapy?



Isolation Therapy



Functional Rehabilitation



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MGA Exoskeleton (MGAXOS)

- Range of Motion
 - scapula elevation (0°/30°)
 - shoulder flex/ext (147°/46°)
 - shoulder abd/add (105°/75°)
 - shoulder rotation (105°/75°)
 - elbow flex/ext (142°/0°)
 - forearm pro/sup (180°/180°)
- Torque Output
 - 137 N-m scapula elevation
 - 137 N-m shoulder rotation (x3)
 - 69 N-m elbow flexion
 - 0 N-m forearm supination
- Link Adjustments
 - clavicle (19.5-26.8 cm)
 - upper arm (27.2-31.2 cm)
 - forearm (23.0-32.0 cm)



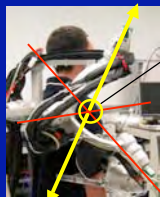
Maryland-Georgetown-Army
Exoskeleton (MGAXOS)

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28

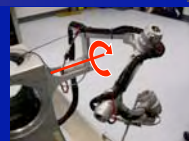
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Key Design Features



3-axis
shoulder
(GH)
rotation

1st axis tilted to prevent gimbal lock when arm straight down



scapula joint for
shoulder elevation

3 adjustable
links for
variable arm
geometry

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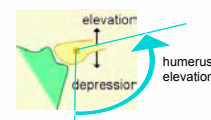
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Scapula-Humeral Rhythm

Refers to the elevation of the shoulder glenohumeral joint (GH) that occurs as the humerus (upper arm) rises

- Caused by rotation of the scapula for elevations below 90°
- GH joint moves on surface of sphere with clavicle radius ~15 cm



(Animation courtesy of Tobias Nef and Rob Riener, ETH Zurich)

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Shoulder Design

GOALS:
 -maximize rotational workspace
 -minimize impact of singularity

Prototype I

Prototype II

would have been Prototype III ...

singular direction

Passive MB Exoskeleton (Wright-Patterson AFB)

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Shoulder Elevation Video

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Patient Movement Ratings

Rating	Strength	Description
0	0%	cannot contract muscle
1	10% (trace)	trace of muscle contraction but cannot move limb
2	25% (poor)	can perform ROM* in a gravity eliminated position
3	50% (fair)	can perform ROM against gravity but no external resistance
4	75% (good)	can perform ROM against gravity and with moderate resistance
5	100% (normal)	can perform ROM against gravity and full resistance

*ROM = Range of Motion

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Movement Modes

MOVEMENT MODE	MUSCLE GRADE	PATIENT ROLE	THERAPIST ROLE
Passive	0, 1	no effort	move limb
Active	2, 3	move limb	no force applied
Isometric	4, 5	maximum effort	immobile
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DEFINITIONS:
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Isokinetic - machine produces velocity-controlled active motion; subject develops resistance only if their effort meets or exceeds the velocity of the device

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Exercise Decomposition

```

  graph TD
    MM[Movement Mode] -- "Active, Isotonic" --> RP[Resistance Profile]
    MM -- "Isometric, Isokinetic, Passive" --> SP[Speed Profile]
    RP --> R[Resistance]
    SP --> TG[Trajectory Generator]
    TG --> T[Trajectory]
  
```

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Example Isolateral Exercises

torso frame

humerus frame

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Operator Interfaces

Isolateral Exercise Control Panel

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Example: Functional Training

Virtual Wall placed in front of subject

Paint roller tracks subject's hand

Exoskeleton pushes back upon contact

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Virtual walls are boring ...

... unless you paint them!

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Future Work

- Pilot testing of MGAXOS for use in a clinical setting for initial intervention
- Develop a hybrid-powered prototype that is mobile and can be used as an assistive (orthotic) or resistive (rehabilitation, training) device
- Enhance functional training for portable prototype using advanced virtual reality graphics (stereovision, etc.)
- Interactive rehabilitation over the internet between patient/doctor or for virtual gaming!!!

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The Rise of the Body Bots

Exoskeletons are strutting out of the lab—and they are carrying their creators with them ...

—Erico Guizzo and Harry Goldstein
<http://www.spectrum.ieee.org/oct05/19/011>

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QUESTIONS???

ACKNOWLEDGEMENT: This research was sponsored by the U.S. Army Telemedicine and Advanced Research Center.

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8.8 News Article: "Engineering the Future: Bioengineering's Fischell Festival features marketable inventions, televised surgery", Diamondback, April 22, 2009

THE OTHER HALF

Lacrosse using last two wins, upcoming ACC Tourney as second half' of season

SPORTS | PAGE 8

MARISSA COME ALIVE

Indie songstress looks to break free of genre trappings

DIVERSIONS | PAGE 6



THE DIAMONDBACK

WEDNESDAY, APRIL 22, 2009

THE UNIVERSITY OF MARYLAND'S INDEPENDENT STUDENT NEWSPAPER

99TH YEAR | ISSUE NO. 131

Engineering the future

Bioengineering's Fischell Festival features marketable inventions, televised surgery

By JEFF NASH
Staff writer

Imagine a control room filled with more than 200 people, watching a live video cast of an open-heart surgery as the operating surgeon talks to a university professor more than 30 miles away — think Microsoft Flight Simulator meets Operation.

More than 400 faculty, students and guests gathered in the engineering building yesterday

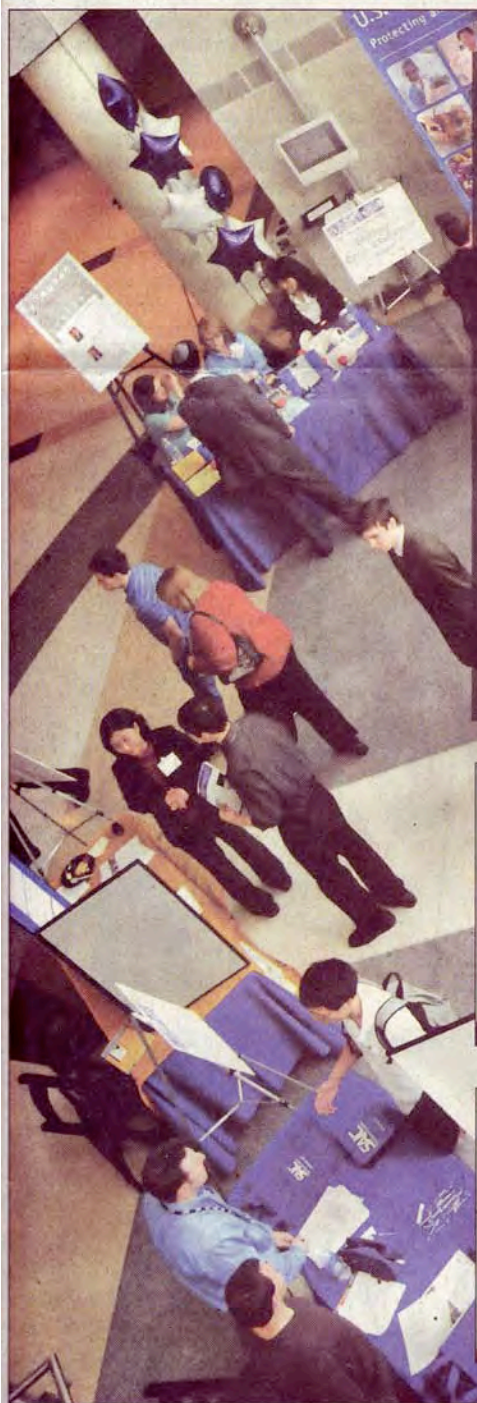
day for the third annual bioengineering Fischell Festival. The eight-hour event included a presentation from scientists about new surgical materials, a live videocast viewing of a heart surgery, a demonstration of a robot exoskeleton, student awards, a bioengineering career fair and various expert discussions.

Hosted by bioengineering department, speakers at the festival ranged from

Please See FESTIVAL, Page 2

Faculty, students and alumni displayed their inventions at the bioengineering festival yesterday, including (clockwise from right) a mechanical arm, a hand strengthening device and a heart stent.

PHOTOS BY MATTHEW CREGER AND JAMES B. HALE/THE DIAMONDBACK



undergraduate inventors to renowned bioengineers to the event's namesake — Robert Fischell, a scientist and engineer who holds more than 200 patents and founded the university's bioengineering department in 2005. The festival's registered guest list more than doubled from the 200 people who attended the first bioengineering festival in spring 2007.

Among the student work on display was an invention created by a team of senior bioengineering majors who won a \$500 prize for their Capstone project: "G.I. Go: Grip It & Go," a hand-strengthening device that could be used by physical therapists to help rehabilitate patients who have lost mobility in their hands.

Seniors Sona Chaudhry, Bryan Hofferbert, D.T. Howarth, Tanya Saleh, and Kim Ziegler said they spent the majority of this semester bringing their idea to fruition. The project beat out eight other inventions, including a dialysis machine and colonoscopy-improving material which both earned runner-ups.

"We had done designs in class, but we had never experienced the communication between engineers and manufacturing before," Chaudhry said. "It was a new experience and we got to learn the [business] processes involved in being an engineer."

The team said a physical therapist told them many patients needed their device, but said they are unsure how much they will be able to market the product because all the members of the team will be graduating in May.

"Students are our lifeblood," said Dr. Bartley Griffith, a professor of surgery at the University of Maryland Medical School. "And bioengineering is the future of our well-being."

A crowd of nearly 200 students, many of whom are medical school-bound, were treated to a live video-cast of a total endoscopic coronary artery bypass surgery — where blood needs to be rerouted around clogged arteries to improve blood and oxygen flow to the heart.

Griffith narrated the surgery while communicating with the doctor, Johannes Bonatti, at the University of Maryland Medical Center in Baltimore.

But this was not a routine open-heart procedure where a patient's breast bone needs to be broken so a surgeon can access



Screens show a live broadcast of a coronary operation from the University of Maryland Medical Center in Baltimore at the Fischell Festival yesterday. JAMES B. HALE/THE DIAMONDBACK

the heart. No bones were broken and Bonatti never even touched the patient. Instead, he directed a four-armed robot, known as DaVinci, to use tiny instruments to cut, tear and burn away at obstructive heart tissue.

Though Bonatti is one of two doctors in the world who is able to use the DaVinci robot to operate on the heart — it is more commonly used for prostate surgery — Griffith said once the technology becomes more streamlined, it could save countless lives.

"With the normal surgery, patients could be out of action for months," Griffith said. "This procedure could have even those with very active jobs back to work in a few weeks."

Though the audience was quiet for much of the procedure, a collective jump rippled through the crowd when a stabilizing tool, no bigger than a pinky-nail, used to hold the heart still during surgery, pierced the heart. When surgery is viewed with the clarity robotic cameras provide, even the tiniest of blood drops look like bursting red balloons.

"It's remarkable that we can sit here in a room together and have this view of the surgery," Griffith said.

"This was definitely better than last year," electrical engineering graduate student Peter Dykstra said. "Last year everyone was standing only to see something inserted into a tumor. There was definitely more detail and action this year."

A slew of inventions were also presented to the crowd including an heart stent and robotic arm.

Robotics professor Craig Carnigan and Georgetown researcher

Jonathan Tang are still working on the invention, but their work probably won't be available to the public anytime soon.

"We'll probably need to build another prototype," Carnigan said. "One reason development is slow is safety. Obviously the goal of it is not to make people more injured, so we need to be really careful because the exoskeleton needs to be strong."

The \$50,000 robotic arm could be used to treat athletic injuries, Carnigan added, but the Army has expressed interest in using it to help rehabilitate soldiers who suffer traumatic brain injuries that often result in a loss of muscle control. Similarly, stroke patients could recover muscle usage and movement ability with the exoskeleton.

Fischell explained how his newest invention, the Svelte Stent — a variation on a life-saving device used to prop open unhealthy heart vessels that minimizes the risk of surgical failure or complications due to its size and composition — can be commercialized and sold. About 98 percent of all stent technologies used nationally are patented by Fischell.

"It's not just engineering, it's not just medicine: It's business," Fischell said, emphasizing technology is useless if it can't be commercialized.

"If you can't get your product out then it has no effect on humanity," Fischell said. "No matter how much research you do, papers you get published or prototypes you create, when people can actually get your product, then you've done something of value."

jnashdbk@gmail.com

8.9 Presentation: "New Technologies for Treating Arm/Shoulder Injury", Booz-Allen-Hamilton Emerging Technologies Focus Group Web Broadcast, May 2009

"New Solutions for Treating Shoulder/Arm Injury: The MGA Exoskeleton"

Craig R. Carignan, Sc.D., CPT

Research Assoc. Prof., Georgetown University
Adj. Prof., University of Maryland
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<http://www.isis.georgetown.edu/caimr/>

Booz|Allen|Hamilton TFG
McLean, Virginia
May 8, 2009



Outline

- Arm Impairment
- Current Best Practice
- Robotic Solution?
- Exoskeleton Description
- Cost/Marketing
- Target Population
- Future Work



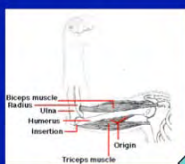
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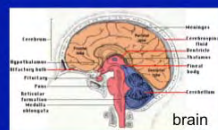
Causes of Arm Impairment

Orthopedic Injury



musculoskeletal system
(accident, surgery,
atrophy, tendonitis)

Neurological Disorder



central nervous system
(brain: stroke, TBI, PD
spinal: SCI, CP, MS)

<http://users.rcn.com/~kimball.ma.ultranet/BiologyPages/C/CNS.html#brain>



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Shoulder Injury — Are you Next?



INJURY LIST:
rotator cuff tear,
dislocated shoulder,
tendonitis,
shoulder separation,
capsule tear,
frozen shoulder,
bursitis,

Shoulder pathology is the leading injury in the upper extremity resulting in 15 million Americans seeking medical treatment each year.



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CNS Disorder Population

Disorder	Current Population	New Cases/Year	Annual Cost (\$B)
Stroke	5,000,000	750,000	69
Alzheimer's Disease	4,500,000	450,000	148
Parkinson's Disease	1,500,000	60,000	6
Spinal Cord Injury	450,000	11,000	21
Traumatic Brain Injury	5,300,000	1,400,000	60
Cerebral Palsy	1,000,000	8,000	12
Multiple Sclerosis	400,000	10,000	8



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U.S. Military Injuries

- Shoulder dislocation is *endemic* in the military population with an incidence of 1.69 per 1000 person-years versus 0.08 per 1000 person-years in the general U.S. population [†]
- As many as 360,000 soldiers who have served in Iraq and Afghanistan suffer from some level of traumatic brain injury due to roadside bomb blasts (\$242M spent on treatment in 2008)

[†]"Incidence of Shoulder Dislocation in the United States Military: Demographic Considerations from a High-Risk Population," Brett D. Owens, MD¹, Laura Dawson, DO², Robert Burks, PhD² and Kenneth L. Cameron, PhD²
The Journal of Bone and Joint Surgery (American). 2009;91:791-796.



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Orthopedic vs. Neuro Therapy

- Neuro-Rehabilitation
 - Central nervous system damaged
 - Movement level 0-3 (barely able to lift arm)
 - Low force, functional retraining
- Orthopedic Rehabilitation
 - Musculoskeletal system damaged
 - Movement level 3-5 (full strength)
 - Moderate force, exercise therapy

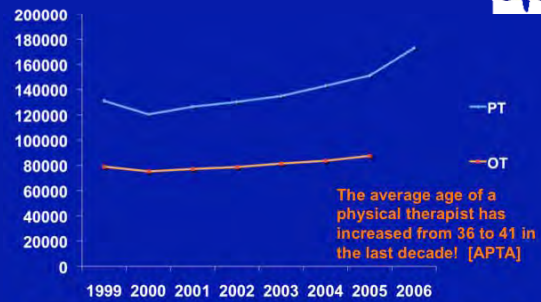


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Physical Therapist Demand



Source: National Center for Health Statistics, Health, United States, 2007, Table 109. Note that estimates do not include self-employed workers.



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oh, oh ... trouble ahead!



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Standard Shoulder Therapy



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Problems with Manual Therapy

- Relies on subject to maintain correct posture
- Patients may require manual assistance during initial therapy
- Motion is typically limited to one direction/axis
- Range of motion may exceed that of subject's
- Resistance does not match subject's strength profile
- Torques realized at the shoulder cannot be accurately controlled
- Little quantitative measure of patient progress



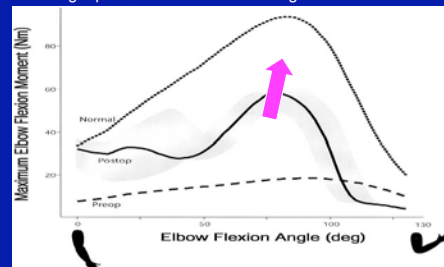
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Abnormal Strength Profiles

Strength profile mismatch due to surgical intervention



K. Saul, W. Murray, V. Hentz, S. Delp, "Biomechanics of the Steindler Flexorplasty Surgery: A Computer Simulation Study", The Journal of Hand Surgery, Nov. 2003; 28A(6).



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Machine Therapy - State of the Art



Biodex System 4 Pro (Biodex Medical Systems, Inc.)

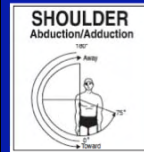


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Shoulder Exercises



Set-Up for Shoulder Ab/Adduction



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Machine Issues

- ❑ Set-up requires adjustment of three components (dynamometer, seat, shoulder attachment)
- ❑ Limited to single axis of rotation for a given exercise (no linear translation)
- ❑ Can only produce constant speed or torque over range of motion
- ❑ Expensive – starts at about \$50,000

Machine is mainly used for isokinetic strength testing in clinical research, not for rehabilitation



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Stroke Rehab – State of the Art



InMotion2 Robot (Interactive Motion Technologies, Inc.)



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Issues

- ❑ Motion is limited to a planar workspace of about 0.5 m²
- ❑ Forces are limited to about 10 N (5 lb) in each direction at the handle
- ❑ Does not support whole arm during therapy so cannot enforce proper shoulder abduction/extension
- ❑ Machine costs about \$70,000

Machine is mainly used for clinical brain research with limited application in stroke rehabilitation



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An Exoskeleton Solution?



Orthopedic



Neurologic



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The Exoskeleton Advantage

- Moves with the arm so it can enforce proper arm motion throughout the exercise
- Forces can be applied at multiple points along limbs to target specific joints/muscle groups for therapy
- Can perform neuro-muscular training through sequential activation of joints
- Can enforce range of motion and torque overload limits



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Exoskeleton Challenges

- Orthopedic rehabilitation can require application of **significant force**
- Needs **adjustable length links** to fit different arm geometries
- **Range of motion** needs to closely match that of the human subject
- System needs to be **fail-safe** to prevent injury to subject



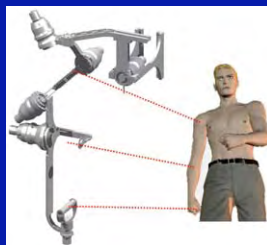
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MGA Exoskeleton (MGAXOS)

- Range of Motion ~ 90% human arm
- Torque Output ~ 110% average adult male
- Link Adjustments - fits 95th percentile population
- Safety System - redundant sensing, NASA compliant



Can be used for Orthopedic and Neural Rehabilitation!



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MGAXOS Overview

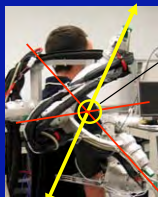


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Key Design Features



3-axis shoulder (GH) rotation

1st axis tilted to prevent gimbal lock when arm straight down



scapula joint for shoulder elevation

3 adjustable links for variable arm geometry



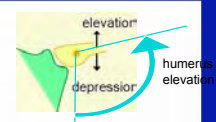
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Scapula-Humeral Rhythm

Refers to the elevation of the shoulder glenohumeral joint (GH) that occurs as the humerus (upper arm) rises



- Caused by rotation of the scapula for elevations below 90°
- GH joint moves on surface of sphere with clavicle radius ~15 cm



(Animation courtesy of Tobias Nef and Rob Riener, ETH Zurich)



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Scapulo-Humeral Rhythm



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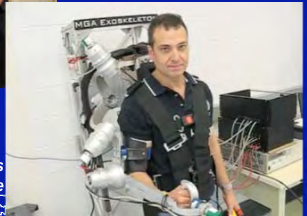
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Shoulder Rehabilitation



body
frame

humerus
frame

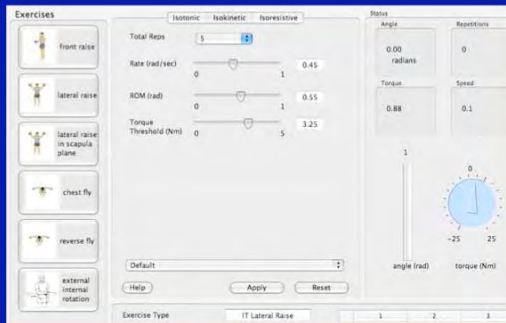


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Exercise Control Panel



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Axes of Rotation



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Exercise Telemetry



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Isokinetic / Isoresistive Modes



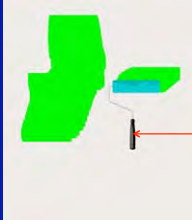
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Neuro-Rehabilitation using VR

Virtual Wall placed in front of subject



Paint roller tracks subject's hand



Exoskeleton pushes back upon contact



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Virtual walls are really boring ...



... unless you paint them!



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Exoskeleton Prototypes



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MGAXOS Advantages

- ❑ High torque capacity (120 N-m @ shoulder) allows for orthopedic and neuro-rehabilitation (most exoskeletons max out at 20 N-m)
- ❑ Link lengths are adjustable for different subjects (not possible in cable-driven designs)
- ❑ Scapula motion allows scapula-humeral rhythm for shoulder therapy and pain-free stroke rehabilitation (natural motion)
- ❑ Portable design (<15 Kg) could be adapted for mounting on backpack



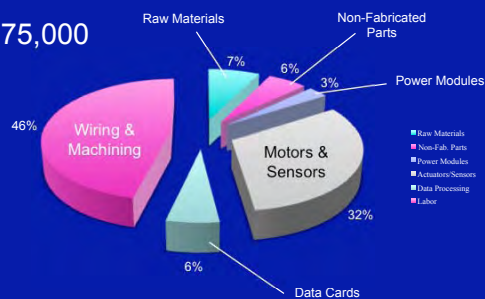
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Cost Breakdown

\$75,000



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Potential Savings

Item	Strategy	Savings
Machining (non-load bearing parts)	Use molded plastics	\$10K
Force-torque sensors (x2)	Uni-axial load cells (x3)	\$8K
Wiring Labor	Prefab wiring harness	\$3K
Incremental Encoders	Reduce resolution	\$2K
Electronics	Card Integration	\$2K
TOTAL		\$25K



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Target Market

- ❑ Inpatient Rehabilitation Facilities (1200)[†]
 - ❑ Acute care (stroke, accident)
 - ❑ Post-surgery
- ❑ Physical Therapy Clinics (12,000)^{††}
 - ❑ Chronic stroke therapy
 - ❑ Sports injuries
- ❑ Physical Fitness Facilities (21,000)^{††}
 - ❑ Prehabilitation
 - ❑ Strength & Conditioning

[†]AHA Annual Survey Database™ Fiscal Year 2007

^{††}U.S. Census Survey (<http://www.census.gov/epcd/ec97/industry/E621340.htm>)



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Current Rehab Device Market

- ❑ Big Players
 - ❑ Biodex Medical Systems (USA)
 - ❑ Hocoma (Swiss)
 - ❑ Motorika Medical (Israel)
 - ❑ HealthSouth (USA)
- ❑ Small Companies/Start-Ups
 - ❑ Interactive Motion Technologies (USA)
 - ❑ Kinetic Muscles (USA)
 - ❑ Saebo (USA)
 - ❑ Aretech (ZeroG)



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Commercial Rehab Robots



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Patent Application

U.S. Patent Application 20070225620



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Future Work

- ❑ Convert software architecture to open source platform
- ❑ Develop additional functional training tasks for stroke rehabilitation
- ❑ Complete integration of safety system components
- ❑ Conduct clinical trial to evaluate operability and effectiveness

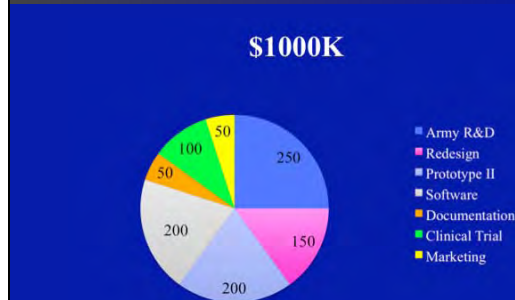


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Cost to Reach Market

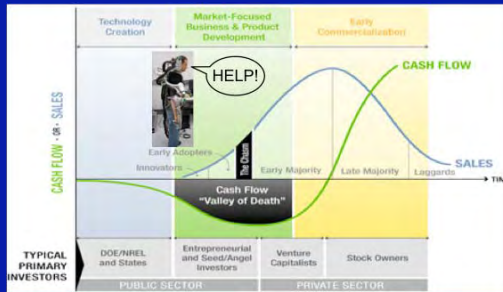


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Traversing the "Valley of Death"



<http://www1.eere.energy.gov/commercialization/abouttheprogram.html>



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B|A|H Health Sector Interests

- U.S. Public Health
 - Spearhead translational research and clinical trials in exoskeleton rehabilitation
 - Develop biomedical informatics grid to collect, analyze, and share therapy protocols
- Wounded Warriors
 - Act as a liaison between the DOD and clinical researchers to address military needs
 - Support development of protocols for treating traumatic brain injury, shoulder rehabilitation, and prosthetic training



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Specific Areas Where You Can Help

- Provide strategic planning for non-profits like GUMC to find private/military investors
- Facilitate clinical trials in exoskeleton therapy to generate ground-breaking advancements
- Leverage NCI Bioinformatics Grid (caBIG) to develop a robotic therapy grid (roBIG?)
- Support efforts to get the insurance industry to "buy-in" to robotic rehabilitation
- Use connections with standards development organizations to develop safety standards and facilitate FDA approval



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The Pitch!

Booz|Allen|Hamilton is known to be a cutting edge, future thinking company with significant interests in the Health Sector. There is no question that robotics and other advanced technologies are going to become a greater presence in 21st century health-care.

This is a good first step at leading the way in this area!



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THANKS FOR YOUR ATTENTION!



The Team:
 Mike Liska
 (Mechanical)
 Jonathan Tang
 (System)
 Stephen Roderick
 (Software)
 Emmanuel Wilson
 (Electronics)
 Mike Perna
 (Machining)
 Joe Hidler
 (Clinical)

ACKNOWLEDGEMENT: This research was sponsored by the U.S. Army Telemedicine and Advanced Research Center.



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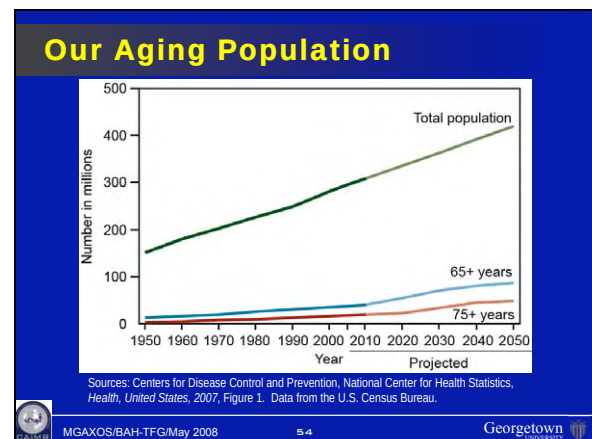
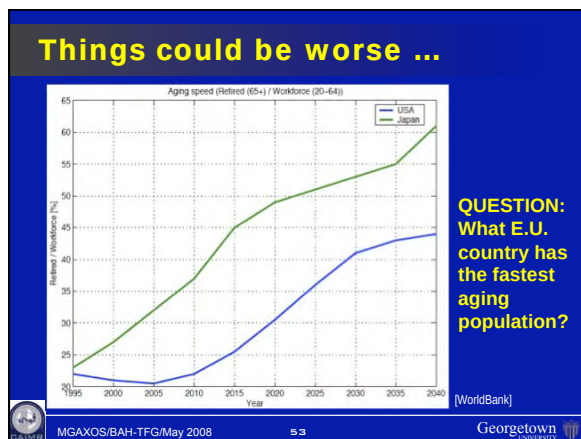
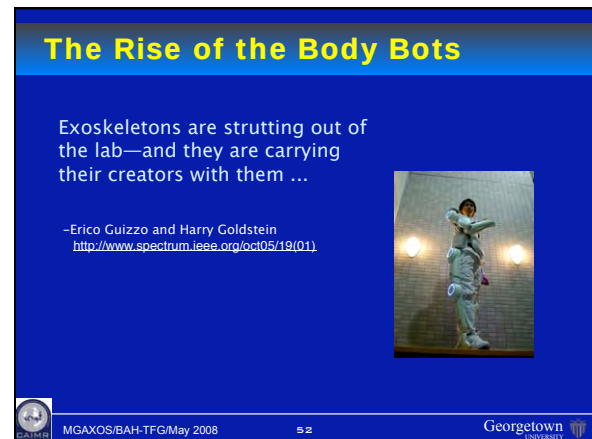
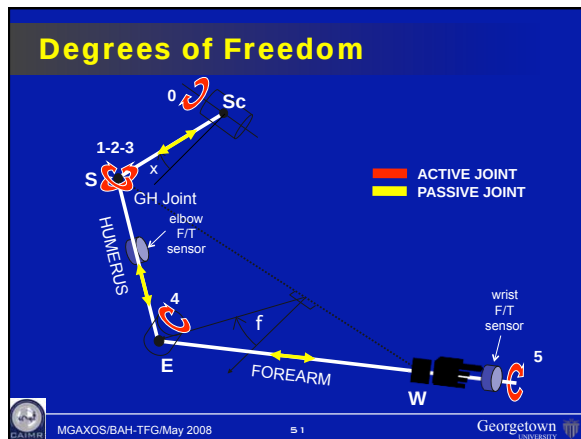
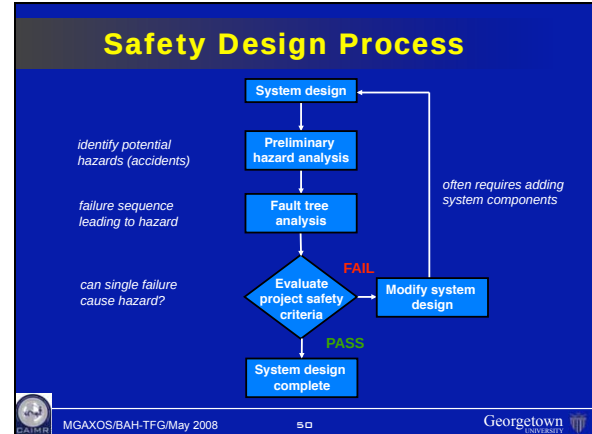
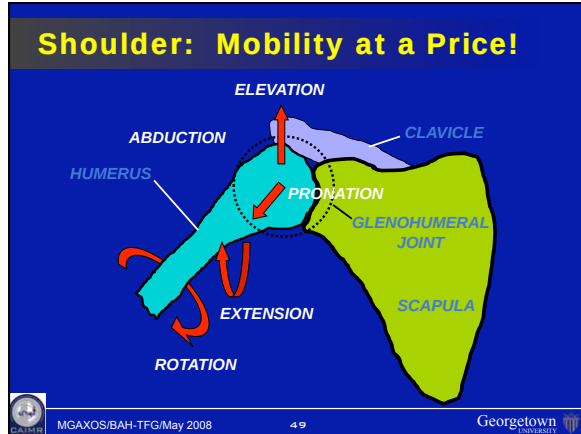
BACK-UP SLIDES



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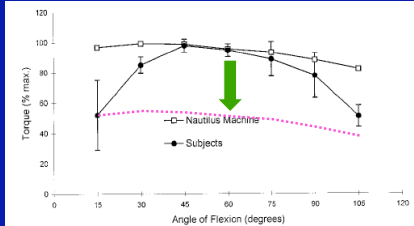
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Matching Strength Profile

Machine resistive torque versus human torque capability at 45°/sec (normalized to percent of maximum).



machine weight must be lowered to accommodate weakest point in range of motion

L. Cabell & C. Zebas, "Resistive Torque Validation of the Nautilus Multi-Biceps Machine", J. of Strength & Conditioning, 1999: 13(1).



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Augmentation Exoskeletons



BLEEX, UC Berkeley

REX, Sarcos/Raytheon, Inc.



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Assistive Exoskeletons



MIT NeuroRobotic Elbow, Myomo, Inc.



ReWalk, Argo Medical Technologies, Israel



HAL 5 exoskeleton, Cyberdyne, Japan.



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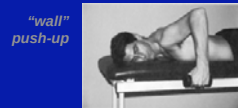
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Shoulder Therapy

ISOLATERAL



shoulder abduction



"wall" push-up

- simple, isolated joint motion
- emphasis on maximum load
- builds muscle strength

FUNCTIONAL



PNF D1 Pattern



ADL Task

- complex motion mimics task
- emphasis on proper movement
- builds coordination & stability



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What Can Robotics Do?

- ❑ Produce consistent force inputs for training and physical therapy
- ❑ Enforce proper motion for given task
- ❑ Prevent torque overload or exceeding safe range of motion
- ❑ Tailor strength profiles for individual patients
- ❑ Provide quantitative feedback on patient progress

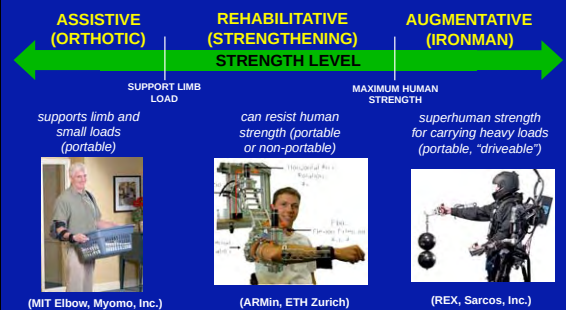


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Exoskeleton Classes



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MGA Exoskeleton (MGAXOS)

Range of Motion

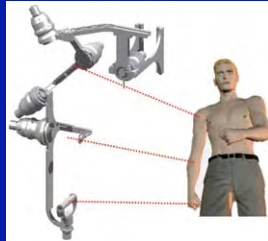
- scapula elevation (0°/30°)
- shoulder flex/ext (147°/46°)
- shoulder abd/add (105°/75°)
- shoulder rotation (105°/75°)
- elbow flex/ext (142°/0°)
- forearm pro/sup (180°/180°)

Torque Output

- 137 N-m scapula elevation
- 137 N-m shoulder rotation (x3)
- 69 N-m elbow flexion

Link Adjustments

- clavicle (19.5-26.8 cm)
- upper arm (27.2-31.2 cm)
- forearm (23.0-32.0 cm)



Maryland-Georgetown-Army Exoskeleton (MGAXOS)



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Patient Movement Ratings

Rating	Strength	Description
0	0%	cannot contract muscle
1	10% (trace)	trace of muscle contraction but cannot move limb
2	25% (poor)	can perform ROM* in a gravity eliminated position
3	50% (fair)	can perform ROM against gravity but no external resistance
4	75% (good)	can perform ROM against gravity and with moderate resistance
5	100% (normal)	can perform ROM against gravity and full resistance

*ROM = Range of Motion



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Instructions: Ab / adduction

Setup and Positioning

1. Seat patient on chair.
2. Attach Shoulder/Elbow Adapter to dynamometer (remove cuff). Insert Shoulder Attachment into Adapter.
3. Align Shaft red dot with R or L and move attachment to almost full abduction. Press Hold.
4. Rotate chair to 90 degrees.
5. Rotate dynamometer to 0 degrees.
6. Raise dynamometer.
7. Tilt dynamometer to 10 degrees.
8. Move patient into position (patient is facing away from dynamometer). Slide dynamometer along travel to align axis of rotation.
9. Check for proper ROM. Keep handgrip loose during motion to allow for the compromising positions of the glenoid humeral joint as it goes through the motions.
10. Stabilize patient with shoulder and waist straps.
11. Set ROM stops.

NOTE: Abduction/adduction is usually one of the last motions exercised in rehabilitation of the shoulder. The clinician must exercise great care in order to avoid impingement.



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Impact on Orthopedic Rehab

- An increasing number of people will incur some type of injury
- Personal trainers will become the primary source for physical therapy
- Non-health professionals will need to know more about rehabilitation and have advanced tools for treatment



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Movement Modes

MOVEMENT MODE	MUSCLE GRADE	PATIENT ROLE	THERAPIST ROLE
Passive	0, 1	no effort	move limb
Active	2, 3	move limb	no force applied
Isometric	4, 5	maximum effort	immobile
Isokinetic	4, 5	maximum effort	apply constant velocity
Isotonic	5	move load	apply constant load

DEFINITIONS:

Isotonic - Subject moves against constant resistance (is lifting a set weight); this can result in either a concentric (shortening) or eccentric (lengthening) muscle contraction

Isometric - machine is static allowing isometric strength to be tested in any given configuration

Isokinetic - machine produces velocity-controlled active motion; subject develops resistance only if their effort meets or exceeds the velocity of the device



MGAXOS/BAH-TFG/May 2008

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Current Robot Safety Standards

STAY OUT OF THE ROBOT'S WORKSPACE!!!

-ANSI/RIA R15.06

WHOA ... you talkin' to me?



MGAXOS/BAH-TFG/May 2008

6.6

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8.10 Presentation: "Shoulder Exercise and Rehabilitation with a Robotic Arm Exoskeleton", NSCA PA State Strength and Condition Clinic, July 2009

ROBOTIC MEDICINE IN THE 21ST CENTURY

"Shoulder Exercise & Rehabilitation with a Robotic Arm Exoskeleton"

Craig R. Carignan, Sc.D., CPT

Research Assoc. Prof., Georgetown University
Adj. Prof., University of Maryland
crc32@georgetown.edu

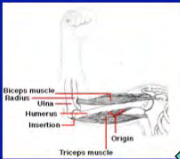
<http://www.isis.georgetown.edu/caimr/>

National Strength & Conditioning Association
Pennsylvania State Strength & Conditioning Clinic
Juniata College, Huntingdon, PA, June 12, 2009



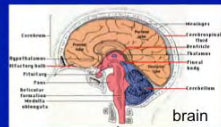
Arm Injury / Impairment

Orthopedic Injury



musculoskeletal system
(tear, impingement, bursitis, dislocation)

Neurological Disorder



central nervous system
(brain: stroke, TBI, PD
spinal: SCI, CP, MS)

spinal cord

<http://users.rcn.com/jkimball.ma.ultranet/BiologyPages/C/CNS.html#brain>

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Shoulder Injury – Are You Next?



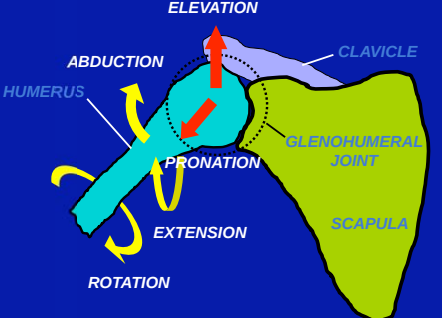
INJURY LIST:
rotator cuff tear,
dislocated shoulder,
tendonitis,
shoulder separation,
capsule tear,
frozen shoulder,
bursitis,

"It's ironic that when we start 'taking care of ourselves' by working out, we often cause injury to the shoulder."
– Brian Schiff, PT, CSCS

Over 15 million Americans seek medical treatment for the shoulder each year making it the leading injury in the upper extremity!

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Shoulder Instability

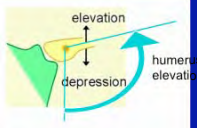


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Scapula-Humeral Rhythm

Refers to the elevation of the shoulder glenohumeral joint (GH) that occurs as the humerus (upper arm) rises

- Caused by rotation of the scapula for elevations below 90°
- GH joint moves on surface of sphere with clavicle radius ~15 cm




(Animation courtesy of Tobias Nef and Rob Riener, ETH Zurich)

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Central Nervous System Disorders

Disorder	Current Population	New Cases/Year	Annual Cost (\$B)
Stroke	5,000,000	750,000	69
Alzheimers Disease	4,500,000	450,000	148
Parkinsons Disease	1,500,000	60,000	6
Spinal Cord Injury	450,000	11,000	21
Traumatic Brain Injury	5,300,000	1,400,000	60
Cerebral Palsy	1,000,000	8,000	12
Multiple Sclerosis	400,000	10,000	8

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U.S. Military Injuries

- Shoulder dislocation is *endemic* in the military population with an incidence of 1.69 per 1000 person-years versus 0.08 per 1000 person-years in the general U.S. population[†]
- As many as 360,000 soldiers who have served in Iraq and Afghanistan suffer from traumatic brain injury due to roadside bomb blasts (\$242M spent on treatment in 2008)

[†]"Incidence of Shoulder Dislocation in the United States Military: Demographic Considerations from a High-Risk Population," B. Owens, L. Dawson, R. Burks, and K. Cameron. *Journal of Bone and Joint Surgery (American)*. 2009;91:791-796.

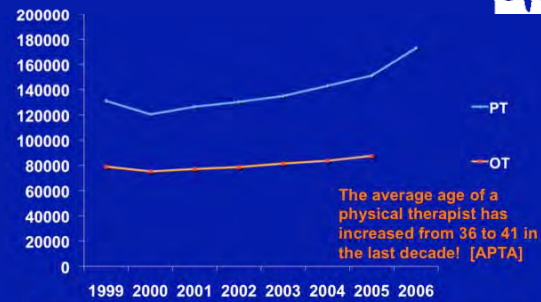


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Surging Therapist Demand



Source: National Center for Health Statistics, Health, United States, 2007, Table 109. Note that estimates do not include self-employed workers.



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Impact on Trainers

- An increasing number of your clients will have some type of injury
- You – and NOT a therapist – will be their long term provider
- You will need to know more about rehabilitation
- You will *want* intelligent tools for assessment and treatment



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Orthopedic vs. Neuro-Rehab

- Neuro-Rehabilitation
 - Central nervous system damaged
 - Low muscle movement level
 - Low force, functional retraining
- Orthopedic Rehabilitation
 - Musculoskeletal system damaged
 - High muscle movement level
 - Moderate force, exercise therapy



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Patient Movement Ratings

Rating	Strength	Description
0	0%	cannot contract muscle
1	10% (trace)	trace of muscle contraction but cannot move limb
2	25% (poor)	can perform ROM* in a gravity eliminated position
3	50% (fair)	can perform ROM against gravity but no external resistance
4	75% (good)	can perform ROM against gravity and with moderate resistance
5	100% (normal)	can perform ROM against gravity and full resistance

*ROM = Range of Motion



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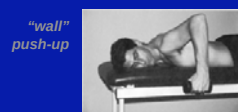
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Shoulder Therapy

ISOLATERAL



shoulder abduction



"wall" push-up

- simple, isolated joint motion
- emphasis on maximum load
- builds muscle strength

FUNCTIONAL

PNF D1 Pattern



ADL Task



- complex motion mimics task
- emphasis on proper movement
- builds coordination & stability



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Manual Therapy Techniques



FREE WEIGHTS



RESISTANCE BANDS



CABLE MACHINES



WEIGHT MACHINES

Georgetown University 13 NSCA-PA Clinic/June 2009

fit

oh, oh ... trouble ahead!

EQUIPMENT FAILURE?

Safeguard Your Shoulders

It's important to know how to make your shoulders safe! Present these painful scenes when you get back into the gym this spring by concentrating some of your strengthening efforts on your control of the shoulder girdle. Addressing the same motor and neuromuscular responses. These four small but significant moves increase neuromuscular activity, providing stability and strength to your entire shoulder joint. They're particularly valuable to wear and tear with age, so the stronger the muscles, the more they can absorb and absorb shock.

On the way of 10 repetitions of each exercise, allowing 30 to 45 seconds of rest between sets. Your movements should be slow and controlled, with one second pause at the top. Do two or three sessions per week.

LOWER EXTREMITY MOVEMENT: Standing with a dumbbell in your right hand, bend your right knee, bend your right elbow 90 degrees, so your upper arm is at your side and your forearm is across your waist. Working your upper arm, lift the weight.

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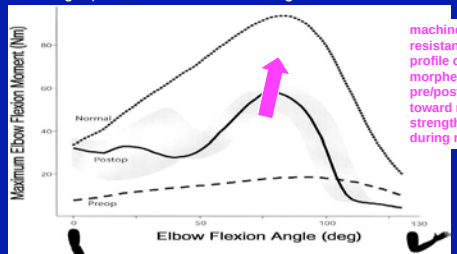
Problems with Manual Therapy

- Relies on subject to maintain correct posture
- Patients may require manual assistance during therapy
- Motion is typically limited to one direction/axis at a time
- Range of motion may exceed that of subject's
- Resistance does not match subject's strength profile
- Torques realized at the shoulder cannot be accurately controlled
- Lack quantitative measure of patient progress

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Abnormal Strength Profiles

Strength profile mismatch due to surgical intervention



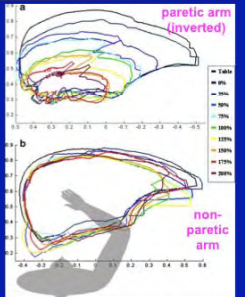
machine resistance profile could be morphed from pre/post-op toward normal strength profile during rehab

K. Saul, W. Murray, V. Hentz, S. Delp, "Biomechanics of the Steindler Flexorplasty Surgery: A Computer Simulation Study", The Journal of Hand Surgery, Nov. 2003: 28A(6).

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Abnormal Synergy Patterns

The reach envelope in hemiparetic stroke patients is reduced by abnormal shoulder abduction/elbow flexion synergy patterns

Shoulder abduction-induced reductions in reaching work area following hemiparetic stroke: neuroscientific implications. T. Sukal, M. Ellis, J. Dewald, Exp Brain Res (2007) 183:215-223

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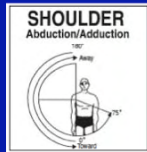
Machine Therapy - State of the Art



Biodex System 4 Pro (Biodex Medical Systems, Inc.)

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Shoulder Exercises



Set-Up for Shoulder Ab/Adduction

Instructions: Ab/Adduction

Setup and Positioning

1. Seat patient on chair.
2. Attach Shoulder/Elbow Adapter to dynamometer (remove cuff). Insert Shoulder Attachment into Adapter.
3. Align Shaft red dot with R or L and move attachment to almost full abduction. Press Hold.
4. Rotate chair to 90 degrees.
5. Rotate dynamometer to 0 degrees.
6. Raise dynamometer.
7. Tilt dynamometer to 10 degrees.
8. Move patient into position (patient is facing away from dynamometer). Slide dynamometer along travel to align axis of rotation.
9. Check for proper ROM. Keep handgrip loose during motion to allow for the compromising positions of the glenoid humeral joint as it goes through the motions.
10. Stabilize patient with shoulder and waist straps.
11. Set ROM stops.

NOTE: Abduction/adduction is usually one of the last motions exercised in rehabilitation of the shoulder. The clinician must exercise great care in order to avoid impingement.

Machine Issues

- ❑ Set-up requires adjustment of three components (dynamometer, seat, shoulder attachment)
- ❑ Limited to single axis of rotation for a given exercise (no linear translation)
- ❑ Can only produce constant speed or torque over range of motion
- ❑ Interaction is limited to the hand or foot
- ❑ Expensive – costs about \$50,000

The machine is primarily used as a dynamometer for isokinetic strength testing, not for rehabilitation

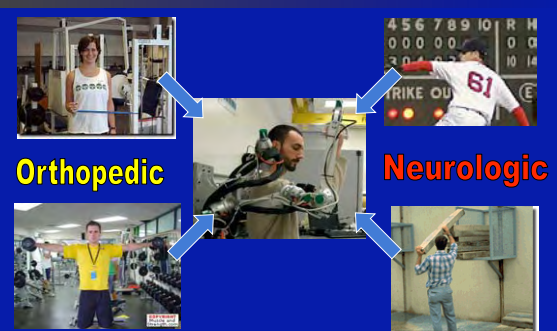
Can Robotics Help?

- ❑ Produce consistent force inputs for training and physical therapy
- ❑ Enforce proper motion for given task
- ❑ Prevent torque overload or exceeding safe range of motion
- ❑ Tailor strength profiles for individual patients
- ❑ Provide quantitative feedback on patient progress

Commercial Rehabilitation Robots



An Exoskeleton for PT?



The Exoskeleton Advantage

- ❑ Moves with the arm so it can enforce proper limb motion throughout the exercise
- ❑ Forces can be applied at multiple points of contact along the arm to target specific joints/muscle groups
- ❑ Can perform functional training to enforce proper neuromuscular activation of joints
- ❑ Can enforce range of motion and torque overload limits

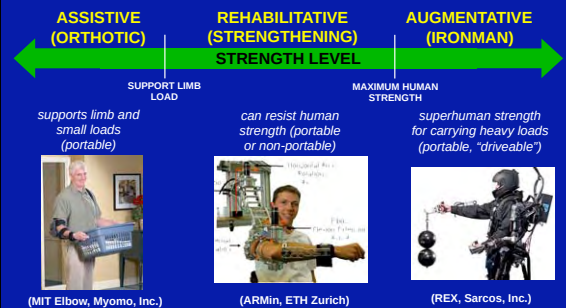


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Exoskeleton Classes

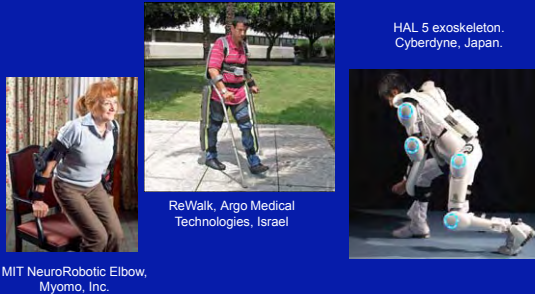


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Assistive (Orthotic) Exoskeletons



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Rehabilitation Exoskeletons



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Challenges for Physical Therapy

- ❑ Orthopedic rehabilitation can require application of **significant force**
- ❑ **Link lengths need to be adjustable** to fit different arm geometries
- ❑ **Range of motion** needs to closely match that of the human subject
- ❑ System needs to be **fail-safe** to prevent injury to subject

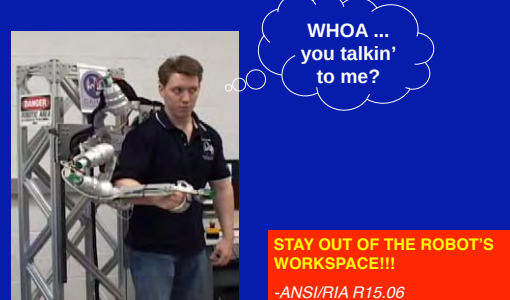


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Current Robot Safety Standards



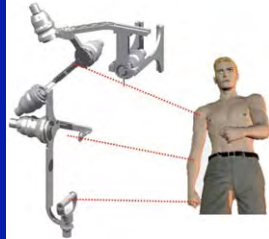
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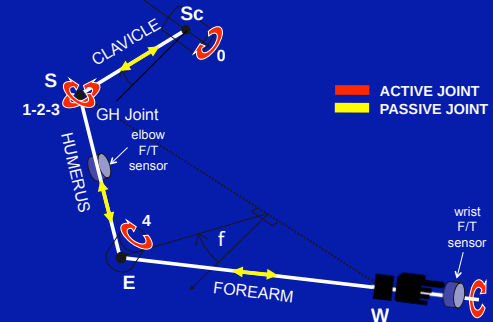
MGA Exoskeleton (MGAXOS)

- Range of Motion ~ 90% human arm
- High Torque ~ 110% average adult male
- Link Adjustments - fits 5th-95th percentile population
- Scapula Motion for shoulder elevation
- Low Weight (<15 kg) - can be made portable
- Fault Tolerant - redundant sensing

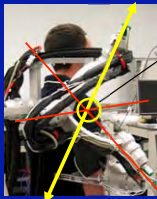


The Maryland-Georgetown-Army (MGA) Exoskeleton

Exoskeleton Anatomy



Key Design Features



3-axis shoulder (GH) rotation

1st axis tilted to prevent gimbal lock when arm straight down



scapula joint for shoulder elevation

3 adjustable links for variable arm geometry

MGAXOS Overview



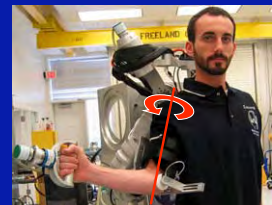
Scapulo-Humeral Rhythm



Frames of Rotation



torso frame

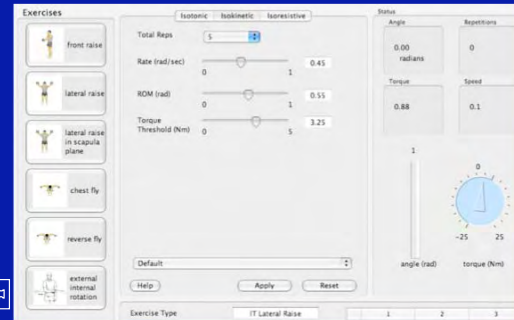


humeral frame

Axes of Rotation



Exercise Control Panel



Shoulder Medial/Lateral Rotation



Shoulder Lateral Raise



Exercise Feedback



Movement Modes

MOVEMENT MODE	MUSCLE GRADE	PATIENT ROLE	THERAPIST ROLE
Passive	0, 1	no effort	move limb
Active	2, 3	move limb	no force applied
Isometric	4, 5	maximum effort	immobile
Isokinetic	4, 5	maximum effort	apply constant velocity
Isotonic	5	move load	apply constant load

DEFINITIONS:

Isotonic - subject moves against constant force or torque, e.g., lifting a dumbbell or a set weight on a cable-pulley machine

Isometric - machine is static allowing isometric strength to be tested in any given configuration

Isokinetic - machine produces constant velocity as long as the force threshold is exceeded; subject exerts effort only if they try to exceed the velocity of the device

Isokinetic / Isoresistive Modes



Functional Training

Virtual Wall placed in front of subject



Paint roller tracks subject's hand



Exoskeleton pushes back upon contact

Virtual walls are really boring ...



... unless you paint them!

Target Market

- Inpatient Rehabilitation Facilities (1200)[†]
 - Acute care (stroke, accident)
 - Post-surgery
- Physical Therapy Clinics (12,000)^{††}
 - Chronic stroke therapy
 - Sports injuries
- Physical Fitness Facilities (21,000)^{††}
 - Prehabilitation
 - Strength & Conditioning

[†]AHA Annual Survey Database™ Fiscal Year 2007
^{††}U.S. Census Survey (<http://www.census.gov/ipeds/data/hesr/2003/industry/E621340.htm>)

Future Work

- Convert software architecture to open source platform
- Develop additional functional training tasks for stroke rehabilitation
- Complete integration of safety system components
- Conduct clinical trial to evaluate operability and effectiveness

THANKS FOR YOUR ATTENTION!



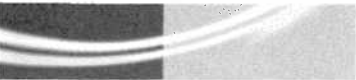
The Team

Mike Liska
 (Mechanical)
 Jonathan Tang
 (System)
 Stephen Roderick,
 Mike Naylor
 (Software)
 Emmanuel Wilson
 (Electronics)
 Mike Perna
 (Machining)
 Joe Hidler
 (Clinical)

ACKNOWLEDGEMENT: This research was sponsored by the U.S. Army Telemedicine and Advanced Research Center.



8.11 IRB Document: MedStar IRB Approval for Clinical Testing at NRH



MedStar Research Institute

MedStar Health

08 August 2008

Joseph Hidler, PhD
National Rehabilitation Hospital
102 Irving Street NW
Washington DC 20010

RE: IRB REVIEW: INITIAL APPROVAL
Project Number: 2008-160
Protocol Title: Rehabilitation of the upper Extremity using a Robotic Arm
 Exoskeleton
Approved Location: National Rehabilitation Hospital

Dear Dr. Hidler:

On 10 July 2008, the MRI Institutional Review Board (#1 Washington Board) requested additional information in order to grant approval for the above-referenced study. The IRB has reviewed and approved the requested information you provided under its expedited review process. Final approval has been granted for the protocol and informed consent document(s) on 07 August 2008.

Approval of this study is valid 07 August 2008 through 02 June 2009. If the study will continue beyond the expiration date, please submit a continuation request form forty-five (45) days prior to the expiration date to allow the IRB sufficient time to review and approve the request.

Please refer to the Office of Research Integrity website at <http://www.medstarresearch.org/Body.cfm?id=243> to review the "Principal Investigator's Responsibilities" as a MedStar researcher.

If you have any questions, please contact me at 301-560-7337 or via email jacqueline.steenbakker@medstar.net.

Sincerely,



Jacqueline Steenbakker
Research Management Specialist

Enclosures: Stamped Informed Consent Document
 Stamped HIPAA Authorization
 Stamped Recruitment Flyer
 Stamped Participant Survey
 Signed IRB of Record Form

Cc: ORI Files
 OCGM

IRB number: 2008-160

Clinical Site IC Version:

Project Title: Rehabilitation of the Upper Extremity using a Robotic Arm Exoskeleton

Principal Investigator: Dr. Joseph Hidler

Institution: National Rehabilitation Hospital

MedStar Research Institute Informed Consent for Clinical Research

INTRODUCTION

We invite you to take part in an investigational research study called "Rehabilitation of the Upper Extremity using a Robotic Arm Exoskeleton". You were selected as a possible participant in this study because you are medically fit to exercise safely (no hypertension or cardiac arrhythmia), you do not have a shoulder injury, and your arm is able to fit in the exoskeleton.

Please take your time to read this form, ask any questions you may have and make your decision. We encourage you to discuss your decision with your family, friends and your doctor(s).

WHAT IS THE PURPOSE OF THIS STUDY?

This study is being done to evaluate the performance of MGAXOS, a robotic arm device that can be used for arm physical therapy. This system will be used to help train patients with shoulder injuries and neurologic injuries such as stroke.

WHERE WILL THIS STUDY TAKE PLACE?

All experimental procedures will take place at the National Rehabilitation Hospital in Washington DC.

WHAT ELSE SHOULD I KNOW ABOUT THIS RESEARCH STUDY?

It is important that you read and understand several points that apply to all who take part in our studies:

- Taking part in the study is entirely voluntary and refusal to participate will not affect any rights or benefits you normally have;
- You will not benefit from taking part in the study, but knowledge may be gained from your participation that may help others; and
- You may stop being in the study at any time without any penalty or losing any of the benefits you would have normally received.

The nature of the study, the benefits, risks, discomforts and other information about the study are discussed further below. If any new information is learned, at any time during the research, which might affect your participation in the study, we will tell you. We urge you to ask any questions you have about this study with the staff members who explain it to you and with your own advisors prior to agreeing to participate.

WHO IS IN CHARGE OF THIS STUDY?

The investigator (person in charge of this research study) is Joseph Hidler, Ph.D., Director of the Center for Applied Biomechanics and Rehabilitation Research at the National Rehabilitation Hospital.

WHO IS THE SPONSOR OF THIS STUDY?

The research is being sponsored by the Department of Defense (DOD) Telemedicine and Advanced Technology Research Center (TATRC).

WHO CANNOT PARTICIPATE IN THIS STUDY?



MedStar Research
Institute

Consent To Participate In A
MedStar Research Institute
Clinical Research Study

Page 1 of 6

Participant Initial _____

IRB Approval Stamp	
(OR USE ONLY - DO NOT CHANGE ANY INFORMATION IN THIS SECTION)	
MedStar Research Institute	
APPROVAL DATE	AUG 07 2008
APPROVAL EXPIRES	JUN 02 2009
IRB APPROVED	
Form Revision Date: 05/10/04	

IRB number: 2008-160

Clinical Site IC Version:

Project Title: Rehabilitation of the Upper Extremity using a Robotic Arm Exoskeleton

Principal Investigator: Dr. Joseph Hidler

Institution: National Rehabilitation Hospital

You cannot be in this study if any of the following applies to you:

- cardiac arrhythmia
- hypertension
- any upper limb impairments
- pregnancy (no pregnancy test will be administered; pregnancy screening will be according to what you tell us)

WHAT IF I AM PRESENTLY PARTICIPATING IN ANOTHER RESEARCH STUDY?

Are you presently participating in any other research studies? Yes ☐ No ☐

If yes, please state which study(ies) _____

While participating in this study, you should not take part in any other research project without approval from the people in charge of each study. This is to protect you from possible injury arising from such things as extra blood drawing, extra x-rays, interaction of research drugs, or similar hazards.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

About 25 people will be recruited for this study.

WHAT HAPPENS IF I AGREE TO BE IN THE STUDY?

If you qualify and agree to take part in this study, you will perform about 45 minutes of manual resistance and functional training and 45 minutes of testing with a robotic arm exoskeleton. Members of the study team will be present during all phases of testing with the robot. At the conclusion of your testing, you will be asked to fill out a one page subject questionnaire to rate your experience with using the exoskeleton.

In the first half of the experiment, you will perform several shoulder exercises using dumbbells and a cable-weight machine and several functional training activities under the supervision of a therapist. For the shoulder exercises, you will perform one set for as many repetitions as possible so that we can determine your one repetition maximum. For the functional training, a study member will first attach optical markers to your arm and upper body using sticky tape in order to track your motion using a motion capture system. Then you will perform several activities of daily living such as lifting a jug of water or opening a drawer, which will later be simulated using the exoskeleton. You may be asked to repeat each of these tasks up to five times.

In the second half of the experiment, you will do testing on the arm exoskeleton under the supervision of a therapist and test engineer. You will stand on the exoskeleton platform with your back against a flat plate. The height of the exoskeleton will then be adjusted by a team member so that its shoulder joint aligns with your shoulder. A five-strap harness will be placed around your abdomen (similar to a race car seat belt) to secure you to a backplate. Your right arm will then be attached to the elbow brace of the exoskeleton using two velcro straps. You will then grasp the handle of the exoskeleton. The exoskeleton will only operate while you depress the switch in the handle. You can stop the exoskeleton at any time by simply releasing the switch.

You will first perform all of the shoulder exercises you did in the first half of the experiment using dumbbells and cable-weights. Prior to each exercise, the therapist will instruct you to move your arm to the start position for that exercise. The exoskeleton will feel very light to the touch and will move in the same direction as the force that you apply to assist you. Once you are in the start position, the therapist will then freeze the exoskeleton position and tell you to let your arm go limp. The exoskeleton will then move your arm through one complete repetition of the



Consent To Participate In A
MedStar Research Institute
Clinical Research Study

Page 2 of 6

Participant Initial _____

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Form Revision Date: 05/10/04	

IRB number: 2008-160

Clinical Site IC Version:

Project Title: Rehabilitation of the Upper Extremity using a Robotic Arm Exoskeleton

Principal Investigator: Dr. Joseph Hidler

Institution: National Rehabilitation Hospital

exercise and return to the start position. The therapist will then instruct you to perform the exercise under your own power. As you move your arm, the exoskeleton will resist your motion and restrict it to a particular path. After you have completed up to five repetitions, the therapist will ask you to stop at the start position and will increase the level of resistance. You will then perform up to five repetitions at the second level of resistance. You will then stop and complete another set at a third level of resistance and go on to the next shoulder exercise.

In the next phase of testing, you will perform the same functional training tasks that you did in the first half of the experiment, but the exoskeleton and a graphical display will be used to simulate the task. A computer monitor will be placed in front of you that displays a graphical representation of the task environment and your right arm. The therapist will then give you instructions for performing the task. For example, "pick up the milk jug on the table and place it in the cupboard." You will then move your arm to "grasp" an object in the virtual environment by moving your hand close to the object. When you pick up objects or contact surfaces, the exoskeleton will apply forces to your arm so that it feels like you are really doing the task. These forces will not be large and will correspond with the tasks that you are doing in the virtual environment. After you complete the task, the therapist may ask you to repeat it several more times before moving onto the next task.

HOW LONG WILL I BE IN THE STUDY?

The entire experiment will take approximately 2 hours to complete, within a single test session.

The investigator may decide to take you off this study if it is believed to be in your best interest, you fail to follow instructions, new information becomes known about the safety of the study, or for other reasons the investigator or sponsor believes are important.

You can stop participating at any time. However, if you decide to stop participating in the study, we encourage you to talk to the investigator first.

If you suddenly withdraw from the study, then we may not be able to use any of the information gathered from your participation because we need data from the tasks being performed both manually and robotically to do our analysis.

WHAT ARE THE RISKS AND SIDE EFFECTS OF THIS STUDY?

If you decide to participate in this study, you should know there may be risks. You should discuss these with the investigator and/or your regular doctor and you are encouraged to speak with your family and friends about any potential risks before making a decision. Potential risks and side effects related to this study include:

Risks and side effects that may occur but are not likely to occur include:

- The exoskeleton and safety system fail, then the exoskeleton could exert full force at full speed until it reaches the end of its range of motion at a mechanical hard stop; note that since the exoskeleton hard stops are within your range of motion, it cannot hyperextend your arm joints.

Risks and side effects that have occurred but only rarely include:

- Exoskeleton fails and goes into fail-safe mode, which is either holding position or powering off.
- Skin irritation from the harness or elbow brace

For more information about risks and side effects, please ask Dr. Hidler.



Consent To Participate In A
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Participant Initial _____

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APPROVAL DATE	AUG 07 2008
APPROVAL EXPIRES	JUN 02 2009
IRB APPROVED	
Form Revision Date: 05/10/04	

IRB number: 2008-160

Clinical Site IC Version:

Project Title: Rehabilitation of the Upper Extremity using a Robotic Arm Exoskeleton

Principal Investigator: Dr. Joseph Hidler

Institution: National Rehabilitation Hospital

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

There are no benefits to you for participating in this study. We hope that the knowledge gained in these tests will help us improve the performance of MGAXOS so that when it is used by patients with arm problems, it will function at the highest level of performance.

WHAT OTHER OPTIONS ARE THERE?

You always have the option of not being in this study.

WHAT ABOUT CONFIDENTIALITY?

Your personal health information (PHI) will be kept private to the extent allowed by law. You will not be identified by name in any publications resulting from this study. You will be asked to sign a separate form that will give permission to the investigator, the sponsor, and certain other people, agencies or entities to look at and review the records related to this study including data collected from your tests and your evaluation form. If you do not wish to sign this permission form you will not be allowed to participate in this study.

Food and Drug Administration, MedStar Research Institute, Inc., representatives of the DOD U.S. Army Medical Research and Materiel Command (USAMRMC) and the National Rehabilitation Hospital which are groups of experts not connected to the study, will be reviewing the data from this research throughout the study. We will tell you about the new information from this or other studies that may affect your health, welfare, or willingness to stay in this study.

WILL I BE PAID FOR PARTICIPATING IN THIS STUDY?

You **will not** be paid for being in this study. Materials and information obtained from you in this research may be used for commercial or non-commercial purposes. It is the policy of National Rehabilitation Hospital, MedStar Research Institute, MedStar Health, Inc., and its affiliated entities not to provide financial compensation to you should this occur.

WHAT ARE THE COSTS?

You do not have to pay anything to be in this study. However, if taking part in this study leads to procedures or care not included in the study, it may lead to added costs for you or your insurance company. You will not be charged for physical therapy time or use of the exoskeleton as part of this research study.

However, you, or your insurance company, will be charged for any other portion of your care that is considered standard of care. You may be responsible for any co-payments and deductibles that are standard for your insurance coverage. This may include physical therapy and use of exercise equipment.

WHAT IF I'M INJURED OR BECOME ILL DURING THE STUDY?

If you are injured because of your participation in this research study, you will be provided medical care for research-related injuries, at no cost to you. Medical care will be provided to you only for the research-related injury and is available at any MedStar facility including the National Rehabilitation Hospital (Washington, DC), Washington Hospital Center (Washington, DC), Georgetown University Hospital (Washington, DC), Harbor Hospital (Baltimore, MD), Union Memorial Hospital (Baltimore, MD), and Good Samaritan Hospital (Baltimore, MD). You will first be required to use your own health insurance for this medical care. You will then be reimbursed for non-covered research-related injury medical expenses, including deductibles. This does not mean that you are giving up your legal rights that you may have as a research



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Clinical Site IC Version:

Project Title: Rehabilitation of the Upper Extremity using a Robotic Arm Exoskeleton

Principal Investigator: Dr. Joseph Hidler

Institution: National Rehabilitation Hospital

participant. You may contact Dr. Joseph Hidler at (202) 877-1892 if you have any questions. You or your insurance company will be charged for continuing medical care and/or hospitalization that are not a part of the study.

If you are hurt or get sick because of this research study, you also can receive medical care at a U.S. Army hospital or clinic free of charge. You will only receive free treatment for injuries that are directly caused by the research study. The U.S. Army does not routinely pay for your transportation to and from the hospital or clinic. If you have questions about this medical care, talk Dr. Joseph Hidler. If you pay out-of-pocket for medical care elsewhere for injuries caused by this research study, contact Dr. Joseph Hidler. If the issue cannot be resolved, contact the U.S. Army Medical Research and Material Command (USAMRMC) Office of the Staff Judge Advocate (legal office) at (301) 619-7663/2221.

Other than medical care that may be provided, and any other payment stated specifically in this consent form, there is not expected to be any other compensation available for your participation in this research. No funds have been set aside, by the National Rehabilitation Hospital, the MedStar Research Institute, MedStar Health, or its affiliated entities to repay you in case of injury, illness, or other harm occurring during, or resulting from the study and their current policies do not provide for payments for lost wages, cost of pain and suffering, or additional expenses. By agreeing to this you do not give up your rights to seek compensation in the courts.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

- You have the right to be told about the nature and purpose of the study;
- You have the right to be given an explanation of the exactly what will be done in the study and given a description of potential risks, discomforts, or benefits that can reasonably be expected;
- You have the right to be informed of any appropriate alternatives to the study, including, if appropriate, any drugs or devices that might help you, along with their potential risks, discomforts and benefits;
- You have the right to ask any questions you may have about the study;
- You have the right to decide whether or not to be in the study without anyone misleading or deceiving you; and
- You have the right to receive a copy of this consent form.

By signing this form, you will not give up any legal rights you may have as a research participant. You may choose not to take part in or leave the study at any time. If you choose to not take part in or to leave the study, your regular care will not be affected and you will not lose any of the benefits you would have received normally. We will tell you about new information that may affect your health, welfare, or willingness to be in this study.

WHO DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury, contact the investigator, Dr. Joseph Hidler at 202-877-1892. If you are having a medical emergency, you should call 911 or go directly to the nearest emergency room.

For questions about your rights as a research participant, contact the MedStar Research Institute. Direct your questions to the Office of Regulatory Affairs at:

Address: MedStar Research Institute
6495 New Hampshire Avenue
Suite 201
Hyattsville, MD 20783

Telephone: (301) 560-7339
Toll Free: (800) 793-7175
Fax: (301) 560-7336



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Institution: National Rehabilitation Hospital

SIGNATURES

As a representative of this study, I have explained the purpose, the procedures, the possible benefits and risks that are involved in this research study. Any questions that have been raised have been answered to the individual's satisfaction.

Signature of Person Obtaining Consent

Date of Signature

I, the undersigned have been informed about this study's purpose, procedures, possible benefits and risks, and I have received a copy of this consent. I have been given the opportunity to ask questions before I sign, and I have been told that I can ask other questions at any time. I voluntarily agree to be in this study. I am free to stop being in the study at any time without need to justify my decision and if I stop being in the study I understand it will not in any way affect my future treatment or medical management. I agree to cooperate with Dr. Joseph Hidler and the research staff and to tell them immediately if I experience any unexpected or unusual symptoms.

Participant's Signature

Date of Signature

Signature of Witness

Date of Signature



Consent To Participate In A
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Form Revision Date: 05/10/04	

RESEARCH AUTHORIZATION TO USE AND DISCLOSE HEALTH INFORMATION

Who may have and use my health information?

I agree to allow **Dr. Joseph Hilder, Dr. Craig Carignan**, and their staff (together called "Researchers"), as well as (when applicable) the other people or companies listed below, to receive, use, have and disclose my personal health information (as permitted below) for the reason(s) described in the Informed Consent Form used for this study (identified above) and as needed to conduct the research.

- The study Sponsor (**U.S. Army**), including others working with the Sponsor (together called the "Sponsor");
- Laboratories and other individuals and organizations that look at my health information in connection with this study;
- Members and staff of the Institutional Review Board(s), Ethics Committee(s), Data Safety Monitoring Boards (DSMB) and all other review boards or persons who watch over how the research is performed and/or monitor the safety and success of the research, including the Institution that approves this study;
- The Patient Advocate or Research Ombudsman (people who watch out for my best interest);
- The United States Food and Drug Administration (FDA), any other Federal or State Agencies that watch over the safety of the study and how the study is managed or run, and/or governmental agencies in other countries which fill similar oversight roles;
- Others: _____

Who may give (release or disclose) my health information?

I wish to allow the **National Rehabilitation Hospital**, all my doctors and my other health care providers, and others who generate or use my health information, to give my health information in my medical or other records to the Researchers, Sponsor(s) and others listed above, for the research purposes described in the Informed Consent Form used in this study and as otherwise described below.

What health information may be used for this research study? (Check all that apply)

- ☐ All my personal information in my medical records or other health care related records requested by the Researchers to be able to do the research described in the Informed Consent Form for this study;
- ☐ All my personal information made or collected during the research described in the Informed Consent Form for this study; and/or
- ☐ Only the following information: _____

***Note: if any of the above records contain any information about HIV/AIDS status, cancer diagnosis, drug/alcohol abuse, sexually transmitted disease, or includes records or information from another healthcare provider, I agree that I am hereby authorizing the release and use of this information.**

What could happen if I agree to this use or disclosure of my health information?

- There is the possibility that Federal privacy laws (laws that protect the privacy of my personal health information) may no longer protect it from being given to another person, class of persons, and/or company.
- Once information that could be used to identify me has been removed and my information is no longer identifiable (connected to my identity), the information that remains is no longer protected by this Authorization (agreement) and may be used and given by the Researchers and Sponsor to others, including for other research reasons.
- The Researchers and Sponsor have agreed that no publication or presentation of the research will reveal my identity without my separate specific written permission and authorization (agreement) (even if I revoke (take back) this Authorization (agreement)).

What rights do I have?

- While my health care and benefits relating to healthcare outside the study will not be affected if I do not sign this form, I understand I have the right to refuse to sign this Authorization (agreement), but that I will not be able to participate in the research referred to in this form.
- I may change my mind and cancel this agreement at any time. To cancel this agreement, I must write to: **Dr. Joseph Hilder, National Rehabilitation Hospital, Room 1060, 102 Irving St. NW, Washington, DC 20010**. However, if I cancel this agreement, I may no longer be allowed to participate in the research and may no longer receive research-related treatment. Also, even if I cancel this agreement, the information already obtained may remain a part of the research as necessary to preserve the integrity of the research study.
- I will be given a copy of this agreement after I have signed it.

When does this Authorization expire?

This Authorization has no expiration date, but shall expire at the end of the research study identified above.

By signing below I represent and warrant that I have authority to sign this document and authorize the use or disclosure of PHI and that there are no restrictions that would prevent me from authorizing the use or disclosure of this PHI.

Signature of Participant (or Participant's Personal Representative)

Date

Printed Name of Participant (and if applicable print name of Participant's Personal Representative)

Representative's authority to sign for Participant, (parent, guardian, power of attorney for healthcare, etc.)



MedStar Research
Institute



Georgetown University

MedStar Research Institute	
APPROVAL DATE	AUG 07 2008
APPROVAL EXPIRES	N/A

IRB APPROVED 2.8.07. v.7

Volunteers Needed to Test Robotic Exoskeleton for Physical Therapy

Would you like to test out a new robotic arm exoskeleton being developed for physical therapy?

Then you might qualify if you're over 18 years of age and don't have any of the following conditions:

- cardiac arrhythmia
- hypertension
- upper limb impairment
- pregnancy (your testimony used for screening)

Where is it being tested? the National Rehabilitation Hospital

How long will it take? about 2 hours

What would I have to do? You will do shoulder therapy exercises and some functional training while wearing a robotic arm exoskeleton.

Why should I do it? To help us develop robotic devices to rehabilitate people with shoulder injuries and other disabilities.

Who is conducting the study? Joseph Hidler, Ph.D. (NRH)
& Craig Carignan, Ph.D. (Georgetown University)



MedStar Research Institutional
APPROVAL DATE **AUG 07 2008**
APPROVAL EXPIRES **JUN 02 2009**
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**NATIONAL REHABILITATION HOSPITAL
CENTER FOR APPLIED BIOMECHANICS AND REHABILITATION RESEARCH
102 IRVING ST. NW, RM. 1261, WASHINGTON DC
(directions: <http://www.nrhrehab.org>)**

If interested, please call Dr. Hidler at 202-877-1892 or email: hidler@cua.edu
or Dr. Craig Carignan at 202-687-2088 or email: crc32@georgetown.edu

MGA EXOSKELETON SUBJECT SURVEY



AGE: _____ GENDER: Male ☐ Female ☐
 HANDEDNESS: Left ☐ Right ☐ Neither ☐

Please complete the following survey to rate your experience with using the exoskeleton so that we can improve the system for future training. Thanks!

Statement	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
My overall experience with the exoskeleton was good, and I would recommend it to my friends.					
Set-Up					
Exoskeleton links were adjusted right for me.					
Arm cuff and harness were properly adjusted.					
Exoskeleton was adjusted to right height.					
Comfort					
Harness kept my upper body in one place.					
Arm cuff was comfortable and secure.					
Back plate was comfortable.					
Clinical Staff					
Staff was courteous and friendly.					
Staff was knowledgeable and fully answered my questions.					
The safety stop in the handle was explained clearly.					
Each test was explained clearly before we started.					
Shoulder Exercises					
Motion felt smooth and controlled.					
Resistance provided felt right.					
Speed of the exercises felt right.					
Exercise felt similar to testing with dumbbells and cable-weight machine.					
Functional Training					
Exoskeleton forces felt realistic for the task.					
Graphical displays were realistic for the task.					
Visual and force feedback matched up.					
Tasks done with exoskeleton were similar to tasks done manually.					
What did you like most about testing with the exoskeleton?					
What do you think needs to be improved?					

VedStar Research Institute
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MedStar Research
Institute

**Determination / Notification of IRB of Record
for Human Subject Research Projects performed at
Georgetown University, MedStar Health, or
MedStar Research Institute Facilities**



1. Principal Investigator (First, MI, Last): **Joseph M. Hidler**
 a) Title: **Senior Research Scientist** b) ☐ If PI is a fellow/resident, please check box.
 c) Mailing Address: **102 Irving St., Rm. 1060, Washington, DC 20010**
 d) Institution: **National Rehabilitation Hospital** e) Telephone: **202-877-1892**
 f) Department: **CABRR** g) Facsimile:
 h) E-mail: **hidler@cua.edu** i) Pager:
 2. Project Coordinator (First, MI, Last): **Craig R. Carignan**
 a) Title: **Associate Research Professor**
 b) Mailing Address: **2115 Wisconsin Ave. NW, Suite 603, Washington, DC 20057**
 c) E-mail: **crc32@georgetown.edu** d) Facsimile:
 e) Telephone: **202-687-2088** f) Pager:
 3. (for all IRB correspondence): **102 Irving St., Rm. 1060, Washington, DC 20010**
 4. Title of Project: **Rehabilitation of the Upper Extremity using a Robotic Arm Exoskeleton**
 a) Locations where project will be conducted:
 (i) **National Rehabilitation Hospital**
 (ii) (Choose One)
 (iii) (Choose One)
 b) To your knowledge, is this (or a substantially similar) study already being conducted at another MRI Institution?
 (Choose One)
 5. Regulatory Sponsor: **U.S. Army Medical Research and Materiel Command**
 6. Funding Entity: **TATRC** Award Number, if any: **W81XWH-08-2-0010**
 7. Proposed IRB of Record: **MRI Institutional Review Board**
 a) Rationale for Proposed IRB of Record:
All testing and recruitment will be done at NRH; the PI for the study is at NRH

RECEIVED

APR 30 2008

**INSTITUTIONAL
REVIEW BOARD**

Please submit the following to each institution:

- ☒ Two copies of the **IRB of Record Form** (this form)
☒ Two copies of a **detailed summary** of the proposed research protocol
 (Please submit the application form(s) for the IRB that you propose will be
 the IRB of record)
☒ Two copies of the **Consent form** (Please submit the consent form(s) for the
 IRB that you propose will be the IRB of record)
☐ If already approved by the MRI or GU IRB, attach a copy of IRB approval
 documents, including approval letter, IRB-approved consent form, and any
 IRB-approved HIPAA documentation
☒ If not yet approved by the MRI or GU IRB, indicate date new project
 application was submitted to the proposed IRB of record: **4/30/2008**

Address for each Institutional Review Board:

Georgetown University IRB
 SW-104 Med-Dent Building
 3900 Reservoir Road NW, Washington, DC 20057
 (202) 687-1506 (Phone); (202) 687-4847 (fax)

AND

MedStar Research Institute IRB
 6495 New Hampshire Avenue, Suite 201
 Hyattsville, MD 20783
 (301) 560-7339 (Phone), (301) 560-7336 (Fax)

Georgetown University (GU; IRB registration # 00000313, Federalwide Assurance # 00001080) and MedStar Research Institute (MRI; IRB #00000598, FWA #00000504) both link their Federalwide Assurance numbers to each other's Assurance. The officials signing below agree that the designated IRB (or, in some cases, both IRBs) will be responsible for review and continuing oversight of the human subjects research described above, regardless of the MedStar Health facility (ies) in which the research is conducted, and that such review and oversight will meet the human subjects protection requirements of the applicable OHRP-approved assurance. If any additional information is needed, the PI will be notified. The PI should then submit the full IRB application, along with this form to the appropriate institution's IRB.

IRB of Record will be:

☐ GU Only ☒ MRI Only ☐ Both GU and MRI (i.e., dual submission to both IRBs will be required)

Authorized institutional official or IRB chair for GU:

Mary A. Young MD
 Printed/Typed Name and Title

Mary A. Young MD

Authorized institutional official or IRB chair for MRI:

Charles R. MacKay
 Printed/Typed Name and Title

Charles R. MacKay

8.12 IRB Document: Human Subject Test Protocol for Clinical Study

Study Title: Rehabilitation of the Upper Extremity using a Robotic Arm Exoskeleton

Principal Investigator: Joseph Hidler, PhD (PI), National Rehabilitation Hospital, 102 Irving Street NW, Washington DC 20010, (P) 202-877-1892, (F) 202-726-7521

Associate Investigators: Craig Carignan, Sc.D., Peter Lum, Ph.D., Jonathan Tang, M.S., Diane Nichols, P.T., Kathy Brady, P.T.

Sponsor: Department of Defense (DOD) Telemedicine and Advanced Technology Research Center (TATRC)

Location: National Rehabilitation Hospital, 102 Irving Street NW, Washington DC 20010, (P) 202-877-1892, (F) 202-726-7521

A. EXECUTIVE SUMMARY

This pilot study will test the hypothesis that common manual therapy protocols can be effectively implemented on a robotic arm exoskeleton device. This device, called the *MGA Exoskeleton* or "*MGAXOS*", has a range of motion and strength comparable to the average adult male. In addition to testing standard therapy exercises, functional movements will be tested that cannot be executed using current exercise machines. To date, we have already developed the controllers necessary to perform these protocols and have done extensive "unmanned" testing to verify operation. In addition, we developed a computer-controlled safety system to monitor for hazards and shutdown the system in the event of a failure. In this study, we will test 25 healthy subjects with a wide range of arm geometries and strength levels to ascertain fit, comfort, and task execution. Prior to testing with the exoskeleton, each subject will perform the tasks manually while outfitted with optical markers. The range of motion for each segment of the task will be recorded using a motion capture device and the net joint reaction forces and moments will be determined using either direct measurement (e.g. weight machine)

or derived through inverse dynamic models (Hidler, 2006). This data will be used to determine the range of motion and torque requirements for programming the exoskeleton controller. Performance metrics will also be developed and displayed on a graphical user interface to the clinician. Although the main purpose of this pilot study is to validate operation of the device in a clinical setting, a follow-on study is being planned to assess therapeutic outcomes with the device compared to a control group undergoing manual physical therapy.

B. STATEMENT OF PROBLEM AND IMPORTANCE

According to recent statistics, nearly 15 million people seek medical care in the U.S. each year for shoulder problems (Center for Disease Control and Prevention, 2003). Some orthopaedic conditions that are of particular interest include: shoulder impingement syndrome (Peterson and Renström, 2001), rotator cuff tears (McQuade et al. 2004), and ulnar collateral ligament reconstruction a.k.a. Tommy John surgery (Saul et al., 2003). Rehabilitation of shoulder function is intense, time consuming, and painful at times. It is made even more difficult by the lack of tools for quantitative assessment and control of therapy. This need has even prompted NIH to state a primary goal of its current research as "developing and testing the effectiveness of biomechanically based rehabilitation strategies to improve upper extremity function and reduce pain in people with shoulder problems" (NIAMS, 2006).

Upper limb impairment can also be caused by neurological injury due to stroke. Over 700,000 Americans suffer a stroke each year, and by 2050, that number is expected to double (MacKay and Mensa, 2004; United Nations, 2005). Stroke victims treated with a robotic rehabilitation protocol have demonstrated significant reductions in impairment of the exercised limb (Krebs et al., 2000; Fasoli et al., 2004), which supports the theory that activity-dependent plasticity underlies neuro-recovery. Treatment protocols targeted at emphasizing a sequence and timing of sensory and motor stimuli similar to those naturally occurring in daily life could

facilitate carry-over of the observed gains in motor abilities, likely resulting in greater improvements in functional recovery (Lum et al, 2004).

Robotic devices offer several advantages over manual therapy – they do not fatigue so that a large number of repetitions can be practiced, they can apply consistent and precise forces, and they provide quantitative measures of performance. Exoskeletons, which surround the whole arm, are particularly suitable for physical therapy because they can exert forces along the whole limb. The exoskeleton can be used to execute full 3-D motion and apply variable levels of resistance to the arm over the entire workspace thereby allowing a full battery of therapeutic exercises to be applied. This contrasts sharply with traditional linear and cam machines, which restrict movement to a single direction and cannot actively modulate resistance. Task-specific neurorehabilitation using robotic devices can also yield considerable benefits for patients with upper and lower limb impairments by offering precisely reproducible therapies over extended duration.

While robotic devices have been primarily viewed as rehabilitation tools, recent evidence suggests that they are also useful in assessing function and levels of impairment (Hidler et al., 2005). For example in stroke, the common assessment scale is Functional Independence Measure (FIM) (Dodds et al., 1993) and Fugl-Meyer (Fugl-Meyer et al., 1975) – yet each is plagued with errors due to its poor inter-rater reliability and subjectivity. Robotic devices such as arm exoskeletons provide clinicians and therapists with a way of quantitatively assessing the primary contributors of upper extremity impairment, including strength, coordination, range of motion, muscle tone, and spasticity.

C. BACKGROUND AND LITERATURE REVIEW

Current exercise therapy utilizes a variety of passive devices and can be categorized into three regimes: stretching, range of motion (ROM), and strengthening. While stretching is

important to attain relaxation of the muscle, this project will focus on ROM and strengthening exercises. In most instances, strengthening and ROM exercises involve the same motions but are performed with and without resistance, respectively. The movements can be broken down into: (a) rotations about orthogonal axes, and (b) linear, functional movement patterns. In strengthening exercises, resistance is usually provided by free weights, rubber tubing/bands, or manually by a therapist. For example, a typical shoulder strengthening exercise about a shoulder axis is shown in Fig. 1(a). Resistive torque about the external shoulder rotation axis is provided through a moment arm by rubber tubing grasped by the hand. Similarly, the cable-pulley machine shown in Fig. 1(b) can be used to apply forces at the hand for linear patterns (Brumitt et al., 2005). The advantage of the cable system is that it provides a constant tension at the hand over the whole movement. This situation is superior to rubber tubing where the resistance increases as the tubing is stretched often resulting in the largest forces being applied in the weakest range. However, the application of force using cable is still limited to a single direction and the torque realized at the shoulder cannot be modulated during the exercise. Finally, Fig. 1(c) shows a lateral raise being done using a dumbbell. This is an example of an isotonic (constant force) exercise except that it does not result in constant torque about the shoulder due to the variation of the moment arm about the shoulder axis.

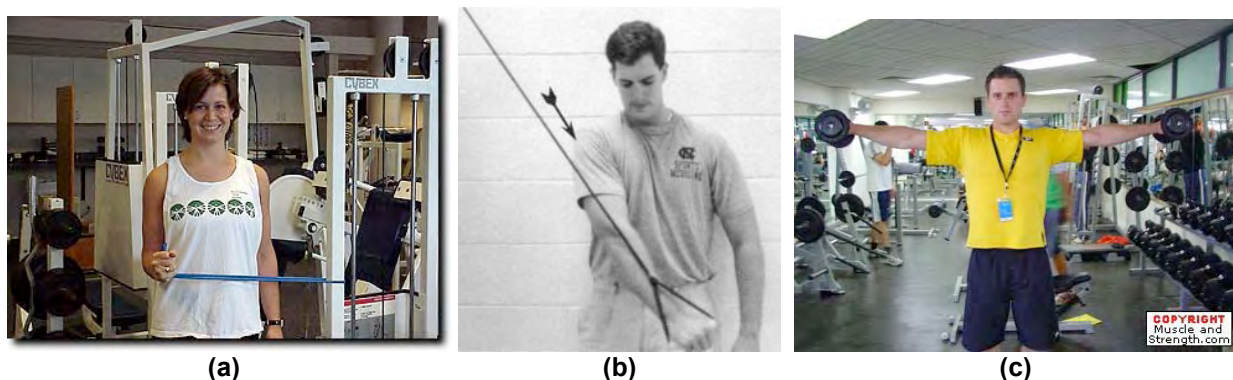


Figure 1: Shoulder exercises: (a) external rotation using rubber tubing, (b) diagonal flexion using a cable-pulley machine, (c) lateral raise using a dumbbell.

Machine-Assisted Therapy

Two U.S. companies, Biodex and Cybex, currently manufacture isokinetic machines that can be used for rehabilitation. These machines allow the operator to modulate the resistance or velocity over the range of motion. Figure 2 shows a subject using an isokinetic device to execute an arm motion in a diagonal plane (Prentice, 1999). Unfortunately, while the resistance can be varied over the range of motion, the hand is locked at the same distance from the shoulder and is restricted to a linear plane. The movement therefore cannot replicate a normal functional movement pattern, which is considered important for rehabilitation; in fact, current literature suggests that deviations from proprioceptive neuromuscular facilitation (PNF) patterns may do more harm than good in therapy (Siff, 2003). Complex 3-D motion and modulation of resistance over the entire range of motion are *both* required in order to realize effective rehabilitation.

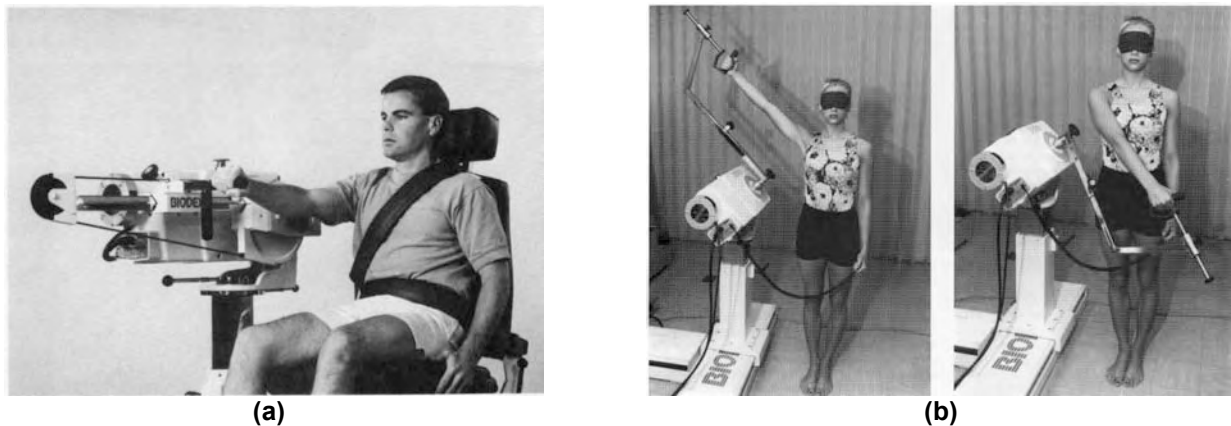


Figure 2: Biodex machine being used for: (a) elbow flexion testing and (b) diagonal movement pattern (Prentice, 1999).

Exoskeleton Devices

Over the past 20 years, several research groups have built arm exoskeletons for use as force-feedback displays in virtual reality applications (Burdea, 1996). More recently, investigators have realized the potential of using exoskeletons for rehabilitation. Because the exoskeleton surrounds the arm, it moves with the patient and can exert forces at attachment points along its

length. These features enable application of fully-articulated 3-D motion and actively-controlled forces at the contact points.

The Robotic Upper Extremity Repetitive Therapy (RUPERT™) shown in Fig. 3(a) is an NIH-supported effort between Arizona State University and Kinetic Muscles, Inc. to build an upper extremity device to help stroke survivors regain the ability to reach and grasp objects (He et al, 2005). The apparatus is portable and lightweight because it is powered by pneumatic muscles. However, RUPERT would have limited application as a shoulder therapy device due to its single powered shoulder degree of freedom (DOF) and the slow response produced by its pneumatic actuators.

The University of Washington Exoskeleton Prototype III, shown in Fig. 3(b), is an electrically-powered seven joint design (Rosen et al, 2003). The goal of this project is to use the patient's own neural command signals obtained through electromyography to control the movement of the exoskeleton. While this exoskeleton is more powerful and responsive than RUPERT, its motors make the arm too heavy to be worn by the patient. In addition, the joints are driven remotely from motors mounted in the base through a system of cables along the links. This rules out the use of adjustable links to tailor the exoskeleton to fit different users.

A serious drawback of both designs is that they only allow shoulder rotation; no translation of the glenohumeral joint is possible. A notable exception is EXARM shown in Fig. 3(c), which is being built for the European Space Agency (ESA) Exoskeleton and (Schiele and Visentin, 2003). This design has six axes in the shoulder assembly, including a spring-loaded prismatic joint. While the design does not limit shoulder-girdle movement, it does not fully actuate it either; three of the joints are passive. Thus while this design incorporates some desirable scapula articulation features, it falls short of producing the forces required for therapeutic interventions.

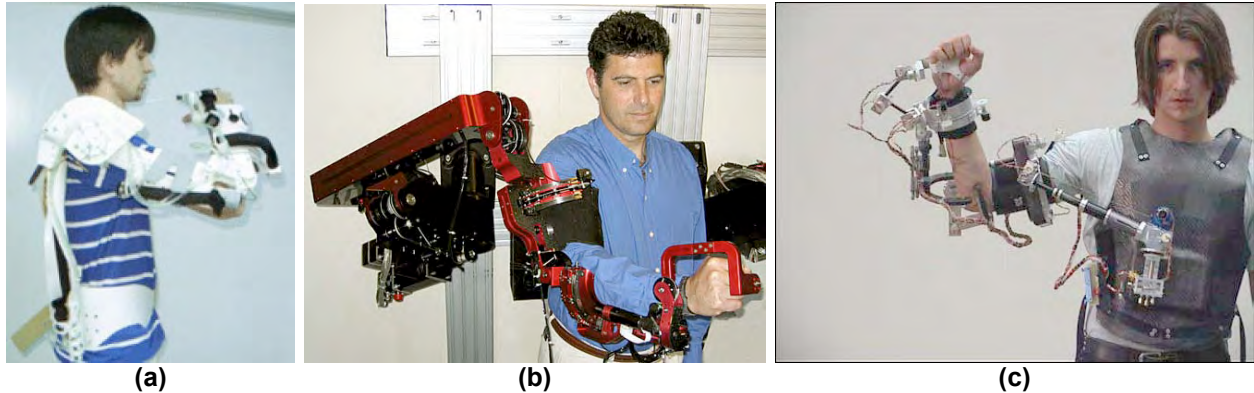


Figure 3: Exoskeletons currently under development: (a) RUPERT, (b) UW III, and (c) EXARM.

MGA Exoskeleton (MGAXOS)

The Maryland-Georgetown-Army (MGA) Exoskeleton is the result of a collaborative effort between Georgetown University and the University of Maryland in 2005/6 to build a post-surgical rehabilitation tool for the U.S. Army Medical Research and Materiel Command (Carignan et al, 2005). The exoskeleton has five powered joints (three shoulder rotations, scapula elevation, elbow flexion), and a single passive joint (forearm roll). Passive link adjustments in the forearm, upper arm, and scapula links allow the exoskeleton to be custom fit to different subjects (Repperger, 1990). A single rotary joint mounted normal to the back is used to approximate shoulder elevation (Buckley and Johnson, 1997). A series of three orthogonal pin joints connected by circular links is used to realize glenohumeral (GH) rotation (see Fig. 4(a)). The elbow joint is approximated as a single pin joint and incorporates a torque-limiting slip clutch that decouples the actuator from the exoskeleton if a predetermined torque value is exceeded. This feature protects the user from injury by allowing free movement in the elbow if a spasm occurs (Johnson et al., 2001).

The forearm roll is the terminal joint on this prototype. It is equipped with an encoder to measure the joint angle, but it is not driven. A mounting bracket for a hand grip is rigidly attached to the forearm link through a six-axis force/torque sensor. The wrist abduction and flexion joints are fixed in the prototype. Dual encoders mounted on the motor and transmission

output provide redundant position measurement for safety. The system is controlled using a single graphical user interface (GUI) panel for the shoulder exercises (see Fig. 5(a)) or a customized GUI for a functional training task. Task parameters such as motion axis, speed, and level of assistance are set using these panels. A software emergency stop is also incorporated in this panel. A second panel (see Fig. 5(b)) is used to monitor data such as position, speed, and forces. Position of the exoskeleton is displayed graphically, while forces are displayed using bar graphs. Threshold limits are also incorporated into the display.

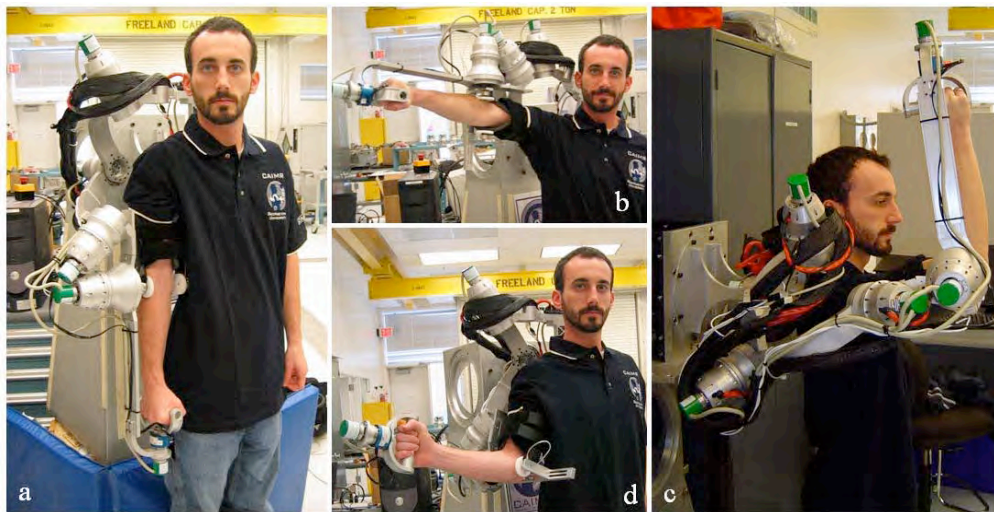


Figure 4: MGA Exoskeleton in several configuration: (a) full shoulder adduction, (b) 90° shoulder abduction, (c) mid-elbow flexion, and (d) full lateral (external) rotation.

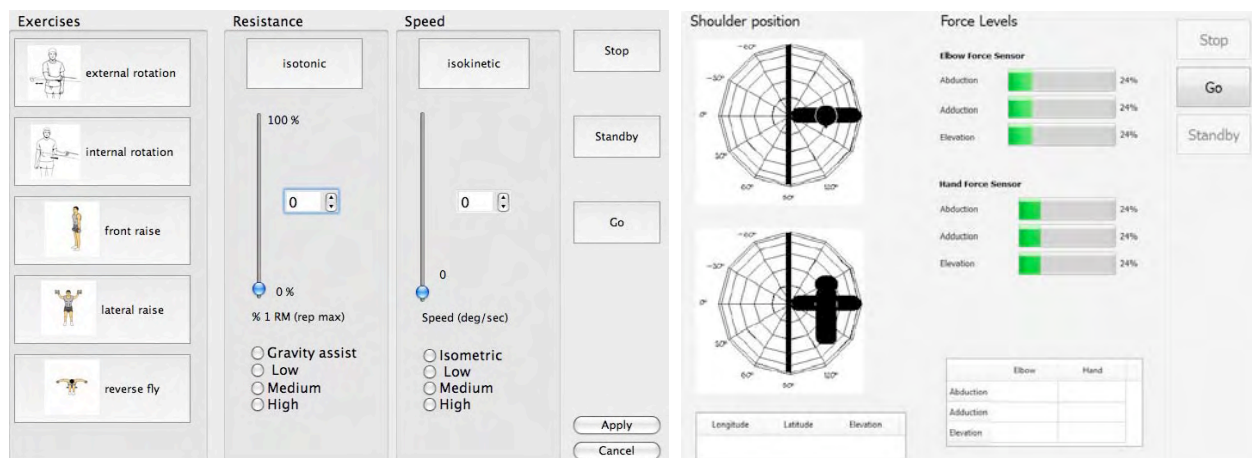


Figure 5: MGAXOS control panel (left) allows the therapist to input parameters for shoulder exercises while the system status and patient metrics are fed back in real-time (right).

MGAXOS Safety Features

Our preliminary hazard analysis conducted early in the design indicated the following three possible hazards:

- A. The patient moves outside their safe position range
- B. The patient moves at an excessive velocity
- C. The exoskeleton applies excessive torque to the patient, or conversely, the patient applies excessive torque to the exoskeleton

We have adopted a computer-controlled safety system for MGAXOS based on an approach certified by NASA for robots that fly on the Space Shuttle (Roderick and Carignan, 2005). This strategy utilizes a combination of hardware, software, and a heartbeat monitor on the safety computer to ensure that the system will be able to detect any *single* failure event and autonomously enter a "safe" state, which is either to: (a) actively hold position and not exert any force on the patient, or (b) completely power down the exoskeleton.

In *hardware*, there are two encoders at each joint that are checked against each other and must agree within a fraction of a degree or the system will safe itself. In addition, there is a current monitor on the power amplifier for each motor which must agree with the current command issued by the motor controller to within a certain tolerance or the system will shut down. There is an emergency stop button that can be pressed by the clinician at any time to cut power to the motors. There is also a trigger switch in the handle that the patient can press at any time to cut power to the motors. Figure 6 shows some of the major components added for safety in the MGAXOS after the safety system design was completed (Carignan et al, 2007).

In *software*, a number of safety features are built in. The exoskeleton's position, speed, torque, and force exerted on the subject are all monitored at 125 times per second. If any safety fault is detected (e.g. subject's position is out of range), the system is immediately safed automatically: MGAXOS either goes into a holding mode, where the subject's position is maintained, or the power is cut to the motors, and MGAXOS goes limp. Note that MGAXOS is

somewhat backdrivable so that when the power goes off, it does not freeze but rather drops very gracefully due to the friction in the system. The system can also be safed manually by the clinician at any time using a software safety switch on the graphical user interface. The safety features have been tested under a variety of simulated conditions that mimic human movement and the different failure modes.

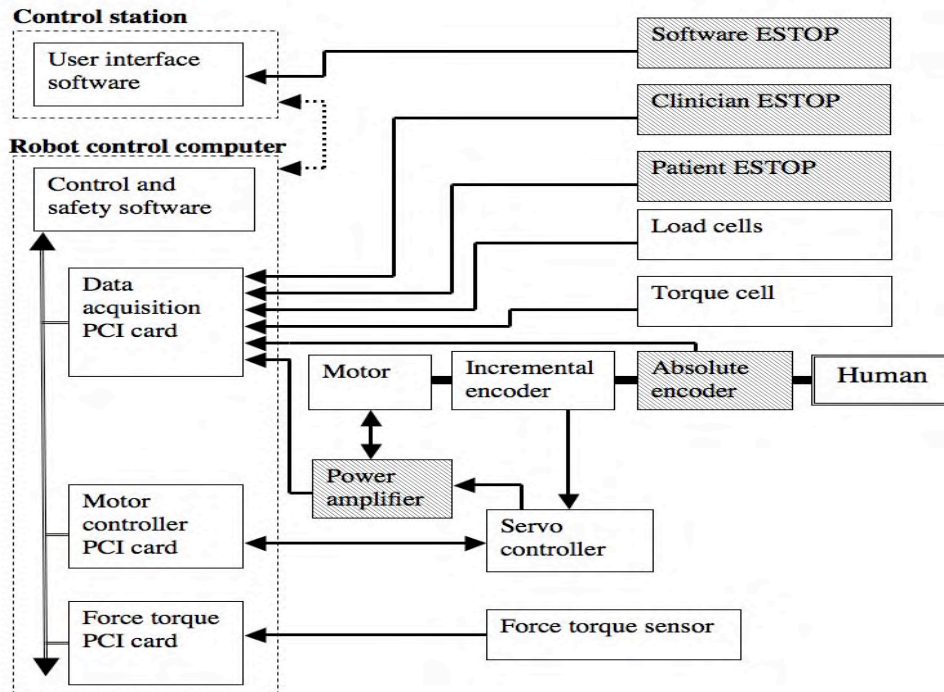


Figure 6: MGAXOS system design showing major components (shaded) for safety: a second (absolute) encoder, a separate power amplifier with current monitor, and emergency stops.

In the event that the system is safed, patient egress is very quick. As demonstrated in the time series of snapshots in Fig. 7, the harness is completely released with a slight turn of the hub on the front of the harness. Once this is released, the velcro strap securing the arm to the humeral cuff is easily torn open completely freeing the subject.

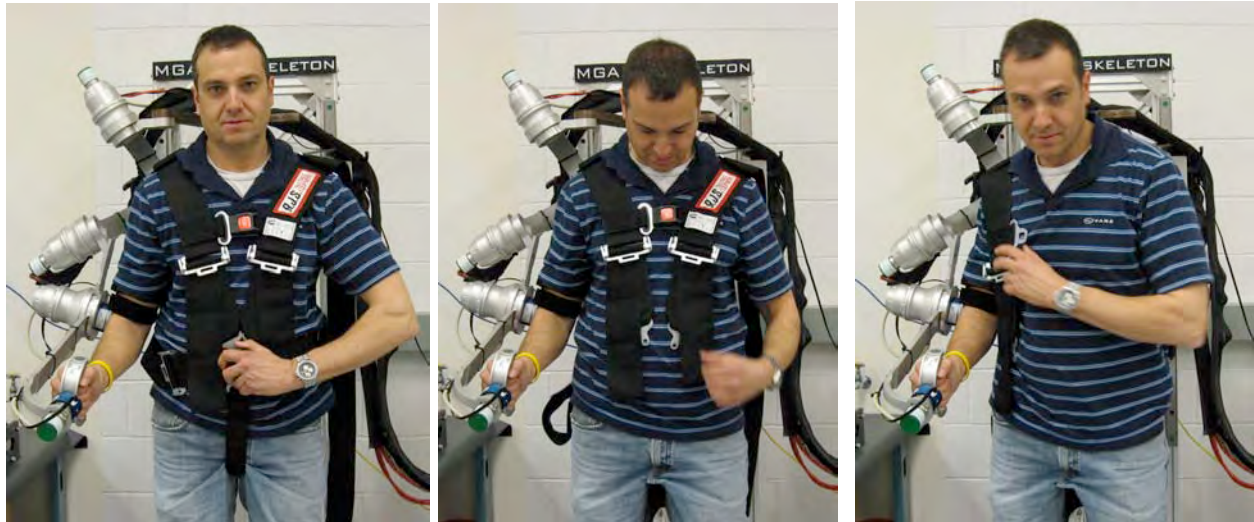


Figure 7: Time series snapshots showing quick release of subject using 5-point harness system.

D. SPECIFIC AIMS

The overall goal of this pilot study is to validate operation of the exoskeleton on a small number of healthy subjects with a wide range of arm geometries and strength levels. The specific aims are:

- Aim 1: Validate the operation of the exoskeleton to perform a variety of exercise protocols using test subjects with a wide range of arm geometries and strength levels.
- Aim 2: Compare measurements of arm kinematics and forces during manual and robotic therapy.
- Aim 3: To evaluate the user-friendliness of the clinical interfaces for operation and monitoring.

E. METHODOLOGY

Subjects

We will test 25 healthy individuals drawn from the therapist pools at the National Rehabilitation Hospital (NRH) and university student populations in the surrounding area. Since the project is a pilot study comparing the exoskeleton with conventional protocols, 25 subjects should give an adequate sample base in terms of arm size, physical strength, and gender. In addition, since the subjects are all healthy, it is expected that their performance will be homogeneous.

Recruitment to the study will be done by word of mouth, coordinated by the investigators on the study. This process has been successful in previous studies run in the PI's laboratory at NRH.

Inclusion criteria

- Subjects must be greater than 18 years old
- Subjects must have no known neurological disorders or current orthopedic injuries that would result in an upper extremity disorder
- Subjects must be able to fit within the adjustable range of the exoskeleton linkages.

Exclusion criteria

- cardiac arrhythmia
- hypertension
- any upper limb impairments
- pregnancy

Note that no pregnancy test will be administered; pregnancy screening will be done in accordance with the subject's testimony.

Recruitment

Subjects will be recruited to the study by word of mouth through the investigators as well as a recruitment flyer to be posted on bulletin boards at the National Rehabilitation Hospital, Catholic

University, and Georgetown University. The flyer will also be circulated in electronic form by email to colleagues of the investigators. At the initial contact, a general overview of the study will be provided to the subject, the benefits and risks, and expected outcome of the study. Any questions by the candidate participant will then be answered. If the subject agrees in principle to participate in the study, upon arrival to the lab at NRH, the physical therapist along with the Principal Investigator will clearly outline the study to each participant. They will describe how long they will be in the study, what to expect during the experimental session, and answer any questions the subject may have pertaining to participating in the study. The PI and therapist will also ask the subject whether they meet the inclusion/exclusion criteria. They will ask the subject whether any of the study exclusion criteria are valid for the subject and will take some basic measures of the subject's arm length and circumference should there be a question regarding whether the potential subject will fit in the MGA exoskeleton. Subjects will also be told that because the exoskeleton is for the right arm some of the tasks might be more difficult to do if they are left-handed. After all of their questions are answered, the subject may decline to participate, can give consent, or may opt to take the consent form home for further review or discussion with friends or family. If the subject agrees to participate, they will be required to give informed consent approved by the Institutional Review Boards of Medstar Research Institute and the U.S. Army Medical Research and Materiel Command's (USAMRMC) Human Research Protections Office (HRPO). The original signed copy of the consent form will be placed in the study binder and the patient will be given a copy for their records. Although we are not collecting any personal health information, subjects will also be required to sign a HIPAA Authorization form so that we can process aggregate anthropometric data collected prior to testing and age/gender/handedness from the subject evaluation forms.

Medstar Research Institute is the governing body that handles research conducted at NRH. Both MRI and NRH are owned by Medstar Health. The Federal Wide Assurance number for MRI, who handles all IRB reviews for NRH is FWA00000504.

PROTOCOL

After providing written informed consent, the experimental session will begin. There will be two groups of 10 subjects each: Group A will perform isolateral exercises followed by the functional training, and Group B will perform functional training followed by isolateral exercises. (Note: we anticipate that up to five subjects will not complete the study for various reasons.) Each group will first perform the tasks manually using passive machines and mockups and then using the exoskeleton. Thus, there will be a total of four test sessions for each subject lasting approximately 20 min each with a 5 min rest between sessions. At the conclusion of the tests, the subject will be asked to complete a questionnaire to rate the comfort of the device, difficulty of performing the exercises, realism of the functional training, perceived safety issues, and their overall experience.

Exoskeleton Instructions for Use

The following procedure is used to set-up the exoskeleton for operation:

1. Adjust three passive linkages to proper length for test subject as determined from anthropomorphic measurements
2. Check that all of the sensor, power, and emergency stop cables between the exoskeleton, computer, and control box are connected
3. Move each joint by hand to verify that the joint angle telemetry to the control station (CS) is correct
4. Apply forces/torques to the force sensors by hand to verify that the telemetry is correct

5. Turn power supply on and verify that all of the power amplifier status lights are in ready state and that all of the emergency stops cut off power
6. Command each joint position individually from the control station to verify that it operates
7. Command straight line trajectories to verify Cartesian motion is functioning properly
8. Apply forces to each force sensors to validate the compliance control is working

The following procedure is used to prepare the subject for testing on the exoskeleton:

1. Subject will stand on a platform and the height of the exoskeleton will be adjusted so that their shoulder joint aligns with that of the exoskeleton
2. Subject's torso will be secured to the backplate using a five-point quick release seat belt harness (RJ Racing, Inc.)
3. Subject's upper right arm will be inserted into an humeral cuff and secured with a velcro strap (see Fig. 10)
4. A computer monitor is placed to the left-front of the subject that displays their arm position in a virtual environment (Tang et al, 2006)
5. Subject will grasp the exoskeleton handle, depress the safety trigger, and perform shoulder and/or elbow movements while the exoskeleton resists or assists motion (Carignan et al, 2008)

The following safety features are built into the exoskeleton design:

1. Hard limit stops on the joints will generally keep the exoskeleton in a safe operating range; software limits are used to tailor the safe operating range for individual subjects.
2. If the sensed force or torque at the hand or upper arm exceeds preset thresholds, the system will automatically shut down.
3. If the joint or handle velocities exceed preset thresholds, the system will automatically shut down.
4. The subject must continually depress the safety trigger on the exoskeleton handle or the system will power off.

5. A computer-controlled safety system will continually monitor the system for failures and safely shut the system down if a failure is detected.

Exercise Tasks

The exercise tasks that will be performed in this study are shown in Table 1 along with arm position and load parameters. The position of the upper arm is represented in global coordinates as illustrated in Fig. 8(a) with the shoulder at the center of the globe (Doorenbosch et al, 2003). Longitude represents planes of elevation where the south pole is 0° (arm straight down) and the equator is at 90° (arm horizontal). Latitudes represent the amount of elevation in a plane of elevation. An azimuth of 0° represents the arm pointing straight out to the right side in the equatorial plane as shown in Fig. 8(b), and 90° indicates the arm pointing straight ahead. The orientation of the forearm relative to this latitude is the angle of the upper arm. The body planes are shown in Fig. 9. Most of the hand movement during these tasks occurs in one or more of these planes with the exception of the scapula plane oriented at 30° with respect to the coronal (a.k.a. frontal) plane.

Table 1: Exercise tasks to be tested this study.

Tasks	Upper Arm Position		Movement Plane	Load/ Resistance*
	Latitude	Longitude		
Isolateral Exercise				% 1RM
Arm Extension	0°/90°	90°	Sag	25-50-75
Lateral Raise	0°/90°	30°	Scap	25-50-75
Internal/External Rotation	0°	30°/150°	Tran	25-50-75
Rear Deltoid	90°	90°/0°	Tran	25-50-75
Functional Training				N
Reach to Pop Balloons	90°/120°	30°/150°	Various	10
Lift Jug to Table	0°	0°/90°	Sag/Tran	35/70
Paint Wall with Roller Brush	60°	+60°/-60°	Cor	20/40
Open/Close Drawer	0°/90°	0°	Tran	25/50

*% of 1 rep max or hand force

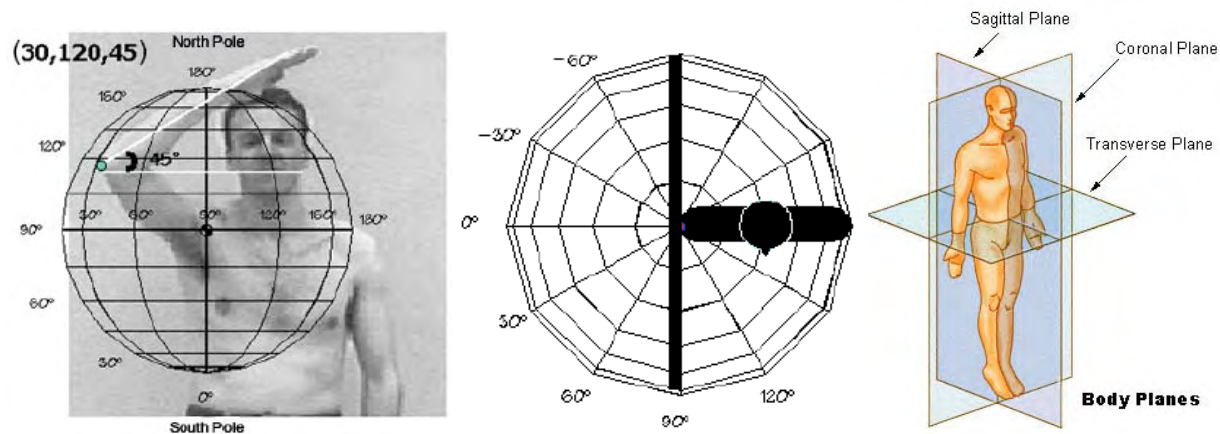


Fig. 8: Global coordinate system used to represent arm configuration: Fig. 9: Body planes. (a) front view, and (b) equatorial plane.

In manual testing, the subject will first perform all of the shoulder isolateral exercises using dumbbells and a cable-pulley machine to estimate their one repetition maximum (1RM). After completing the shoulder exercises, the subject will then perform the functional training tasks using mockups of the actual task. While performing the functional training tasks, subjects will don optical markers to record movement using a motion tracking system (Optotrak Certus, Northern Digital Inc.). Each task will be performed up to five times at the discretion of the physical therapist.

In exoskeleton testing, the subject will stand on a platform and their torso will be secured to a backplate using a five-point harness, and the exoskeleton will be strapped to their elbow using velcro enclosures (see Fig. 10). All tasks will first be done passively where the subject lets the exoskeleton move their arm through the motion. Then the subject will perform the exercise in an active mode where the exoskeleton either resists motion (isolateral exercises) or exerts forces from contacting the virtual environment (functional training). Data will be collected from the exoskeleton to assess movement and forces exerted during the task.

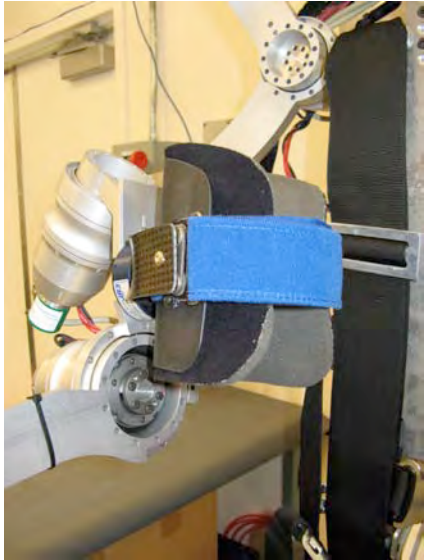


Figure 10: Humeral cuff used to connect subject's upper arm to exoskeleton.

Specific Procedures

Manual Testing – Shoulder Exercises

The purpose of the manual shoulder isolateral testing is to determine the subject's 1RM for each exercise. The 1RM can be estimated from Table 2 by asking the subject perform as many repetitions as possible with a given weight and dividing by the fraction in column 2. For example, if the subject can do 8 reps at 20 lbs, then their 1RM is $20 \text{ lb} \div 0.8 = 25 \text{ lbs}$. If the subject can do more than 10 repetitions, then a larger weight is chosen and the test is repeated after a brief rest period. The following shoulder exercises will be performed:

- (1) arm extension – subject extends arm from home position to 90° elevation in sagittal plane followed by flexion back to home position
- (2) lateral raise – subject abducts arm from home position to 90° elevation in scapula plane followed by adduction to home position
- (3) internal/external rotation – subject rotates arm from straight out in front with the elbow flexed at 90° to their left or right side followed by a rotation back to start position

- (4) rear deltoid – subject abducts arm from 90° elevation straight ahead to straight out by side in the transverse plane followed by abduction to start position

Table 2: Estimating 1 Rep Max.

<i>Repetitions</i>	<i>1 Rep Max</i>
1	1.0
2	0.95
3	0.925
4	0.9
5	0.875
6	0.85
7	0.825
8	0.8
9	0.775
10	0.75

Test Procedure:

- (1) Arm extension/lateral raise. Subject will start with arm down by their side grasping the dumbbell with elbow fully extended; subject will then raise arm in smooth controlled manner with arm fully extended to a horizontal position either in front of them (arm extension) or to the side (lateral raise, Fig. 1(c)) and return arm to start position.
- (2) Internal/external rotation. Subject will start with arm straight down and elbow flexed at 90° directly in front of them; subject will grasp handle connected to cable and rotate their upper arm either outward (external) or inward (internal) in a smooth controlled manner through an angle of approximately 60° and return to start position.
- (3) Rear deltoid. Subject will sit on a weight bench next to a cable pulley machine; subject will raise arm at full extension in front of them and grasp a handle connected to a pulley-weight; subject will abduct their arm outward until it is straight out to their side in a smooth, controlled manner and return their arm to start position.

Manual Testing – Functional Training

The purpose of the manual functional training is to validate range of motion and speed parameters for the exoskeleton and acclimate the subject to the task prior to exoskeleton testing.

Test Procedure:

- (1) Optical markers will be placed at all of the arm joints and at several other points on the arm limbs and upper torso.
- (2) Optotrak receiver is placed at predefined location for the task.
- (3) Test engineer verifies that the motion capture system is working and tasks can begin.
- (4) Paint Wall – subject stands approximately 12 inches from a wall with a sticky mat taped at chest height; using a 6-8 inch laminate roller, the subject "paints" the sticky mat with the roller over a 1 x 2 ft area.
- (5) Pop Balloons – subject grasps short pointer and reaches out to touch various targets in the workspace in front of them.
- (6) Lift Jug – subject lifts a 1 gallon jug of water from a stool at their side and place it on a table directly in front of them.
- (7) Open Drawer – subject reaches out to pull open a filing cabinet drawer placed one foot away directly in front of them and then close it again.

Exoskeleton Testing – Shoulder Exercises

Each of the four shoulder exercises in Table 1 will be performed at 25%, 50%, and 75% of the 1RM, which correspond to "poor", "fair", and "good" on the muscle grade scale (Palmer and Epler, 1998). Subjects will perform up to five repetitions of each shoulder rotation exercise.

Test Procedure:

- (1) prior to each exercise, the subject will put their arm in the start position for the exercise while the exoskeleton is in accommodation mode (exoskeleton moves slowly in same direction as applied force)

- (2) after the subject is in the start position, the therapist will instruct subject to let their arm go limp and the exoskeleton will support their arm
- (3) the exoskeleton will then move subject's arm through one complete repetition of the exercise (passive mode)
- (4) after the exoskeleton has returned to the start position, therapist will instruct the subject to complete a repetition under their own power while the exoskeleton resists their motion
- (5) after returning to the start position, the subject may be asked to perform up to five more repetitions at the given level of resistance which is referred to as a "set"
- (6) after the final repetition of the first set, the subject stops at the start position and the therapist increases the level of resistance
- (7) subject performs up to five repetitions at the second level of resistance
- (8) after the completion of the second set, the subject stops at the start position and the therapist increases the level of resistance
- (9) subject performs up to five repetitions at the third level of resistance
- (10) after completion of the third set, the subject will move on to the next exercise.

Exoskeleton Testing – Functional Training

All of the functional tasks performed manually will be replicated in a virtual environment on the computer screen display in front of the subject. The display will show the tracked position of the arm in the virtual environment while the exoskeleton exerts forces in response to contact with virtual objects in the environment (Tang et al, 2006).

Test Procedures:

- (1) Paint Wall – subject must paint a 2 sq. ft. surface of a virtual wall approximately 12 inch in front of them using a 6-8 inch roller brush. The applied force must be within a range of 10-20 N or the surface will not be coated with paint.

- (2) Pop Balloons – subject must reach out with pointer and pop balloons at various locations in the workspace (must support own arm weight $\sim 10\text{N}$).
- (3) Lift Jug – subject must lift a jug from their side and place it on a virtual table in front of them. The jug weighs about 35 N which is equal to a gallon of water.
- (4) Open/Close Drawer – subject must reach out to pull open a virtual drawer and then close it again. The force required to open the drawer will be about 20 N.

Throughout all trials, data will be stored from the MGAXOS instrumentation in digital format. The system stores forces and motion variables (e.g. joint positions, hand force/torque, etc.) during operation, and then allows the user to save this information to file for post-hoc analysis. The data from these test sessions will be saved on the MGAXOS control computer, which is secured with a password. Only members of the study have access to this computer.

F. DATA ANALYSIS

This is a pilot study to validate setup and operation of the exoskeleton. Each subject will only be tested once, so no statistical analyses will be done to assess clinical outcome. The primary outcome measures are the active range of motion (ROM), kinematics, and surface electromyography (EMG) during the functional tasks. Data analyses from the manual trials will be used to determine input parameters for the exoskeleton trials. Data from the exoskeleton trials will be used to assess whether the exoskeleton achieved the same kinematics and muscular effort as in the manual tests.

Manual Trials

For all of the iso-lateral exercises, the amount of weight used (dumbbells, stack plates) and the range of motion will be recorded. This data will be used to determine the maximum range of motion and torque level to use for the isolateral exercises to be performed on the exoskeleton. For the functional training tasks, the subject's arm motion will be recorded using

an Optotrak Certus motion tracking system (Northern Digital, Inc., Waterloo, Ontario). Sensors taped to the upper arm and forearm measure the 3-D position and orientation of the limb segments during the reach. This information is used in a biomechanical model of the arm to calculate the locations of the joint centers of the wrist, elbow, shoulder, and scapula during the movements. The position data will be used to extract the workspace trajectory and the maximum speed for key components of each task such as picking up objects, applying force to a wall, or opening a drawer.. Surface EMG will be recorded from several arm muscles during the movements (Bagnoli EMG system, Delsys Inc, Boston MA) to determine muscular effort exerted while performing the tasks.

Exoskeleton Trials

Joint positions and force-torque sensor data will be recorded continuously at 125 times per second for all tasks performed with the exoskeleton. For the isolateral exercises, the joint position data will be processed to determine the angular rates about each shoulder axis. In addition, the force sensor data from the upper arm and hand will be used to calculate the realized torques about the shoulder joints. For the functional training tasks, the motion of the exoskeleton hand, elbow, and shoulder will be calculated from the joint position data and compared with the motion capture from the same tasks performed manually. Specifically, we will look for large deviations in either position or speed to determine whether the exoskeleton is inhibiting natural motion. If there is a deviation of more than 25%, then we will relocate the task to another position in the workspace that is not so restrictive. Subject evaluations will also be reviewed as the trials are completed to monitor any general comfort or safety issues that might affect future testing.

Subjective Assessments

At the conclusion of their testing, each subject will be asked to fill out a subject questionnaire that rates their level of comfort with using the exoskeleton, how it compares with the manual tasks, and what they would like to see changed or improved. At the conclusion of

the study, test operators will evaluate each of the exoskeleton control panels using a modified Cooper-Harper Rating Scale similar to that shown in Fig. 11 for rating pilot displays (Cumming et al, 2006). Operators will also be asked to comment on any specific issues with the control interfaces and operating procedures and make suggestions for improvement.

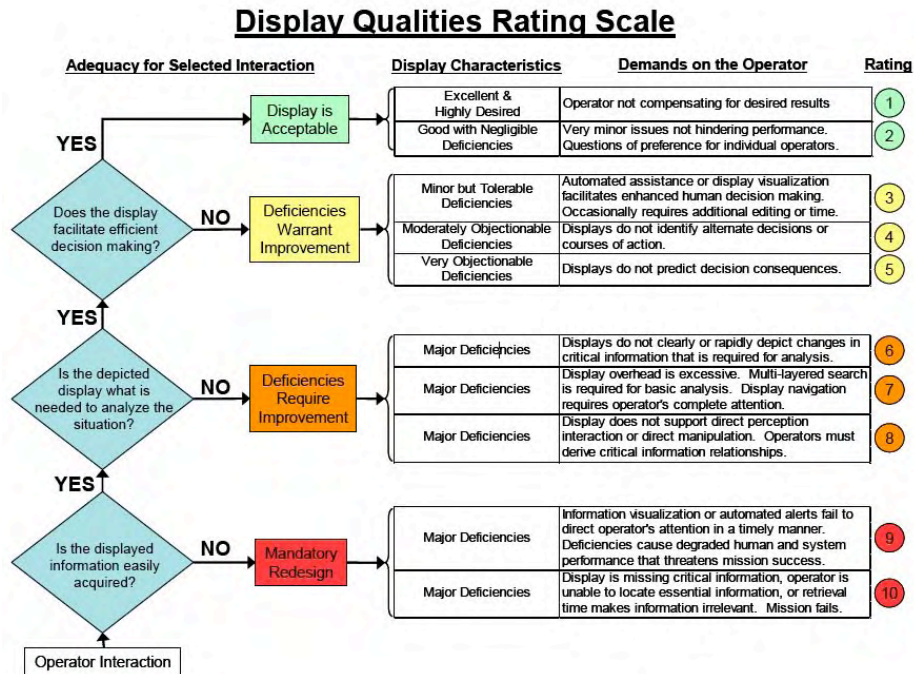


Figure 11: Modified Cooper Harper Rating Scale used for pilot evaluation.

G. EXPECTED OUTPUTS AND DELIVERABLES

Since MGAXOS has undergone extensive bench-top testing replicating the shoulder exercises in unmanned mode both in free space and under load, we believe that the system will perform up to standard under realistic conditions. We will use the data collected in these trials to fine tune the passive adjustments to different arm geometries and resistance levels in the controllers to average strength values. Subject and clinician assessments will also be tabulated and used to improve the interfaces and operational procedures. The expected output and

deliverable is an optimized MGA Exos system that will be used for training individuals with shoulder and other upper body impairments.

H. TIMELINE

It is expected that the testing of MGAXOS will require up to 4 months. Since we will require both MRI and the USMRMC Office of Research Protections (ORP) Human Research Protections Office (HRPO) approval, we anticipate beginning testing September 15, 2008 and will be completed by January 15, 2009. However, we will request that the study stay open until June 1, 2009 so that we may continue data analysis and document the results.

I. DISPOSITION OF DATA

All data collected throughout this research effort will be stored with the Principal Investigator (Dr. Joseph Hidler), and will be kept in strict confidence. No participant identifiable information will be used in any publications resulting from this study. For tracking purposes and for maintaining participant confidentiality to the greatest degree possible, each subject will be assigned a unique patient ID number upon entering the study. After completion of each test session, all patient information will be kept locked in Dr. Hidler's office and will only be accessible to members of the researchers affiliated with this study. Representatives of the U.S. Army Medical Research and Materiel Command are eligible to review research records as a part of their responsibility to protect human subjects. Data and all materials related to the study will be saved for 6 years, after which it will be destroyed by the PI. Forms will be shredded while experimental data will be deleted from the PI's computer.

J. ROLES AND RESPONSIBILITIES OF RESEARCH PERSONNEL

Dr. Joe Hidler will oversee all activities of the study, including recruitment, experimental setup and execution, and data analysis. Dr. Craig Carignan will be responsible for the control system and mechanical operation of the exoskeleton. Dr. Peter Lum is an experienced rehabilitation engineer who will assist with operational setup and data analysis, particularly with regard to the functional training related to stroke rehabilitation. Jonathan Tang is a robotics software engineer and will operate the exoskeleton during the experiments. Diane Nichols and Kathy Brady are physical therapists working at the National Rehabilitation Hospital and will assist with the experimental sessions.

K. RISK AND BENEFITS ASSESSMENT

Risks

There are minimal risks associated with the study. As outlined above, MGAXOS has extensive safety features, which monitor the subject's behavior at 125 times/second and will fail-safe in the event of a malfunction. Only healthy subjects are being recruited for enrollment in this study. Through extensive bench-top testing, we have built safety in both hardware and software so the risks of system failure causing the subject to move out of range or the exoskeleton to apply excessive force are very low. In the event of failure, the system defaults to either a holding position, which prevents the subject from moving, or a power-off position in which exoskeleton will go limp. Subjects may experience some skin irritation due to the harness and humeral cuff, however in the 7 years we have been training subjects in our lab using lower limb exoskeletons, we have not had any harness injuries or skin abrasion due to limb attachments. We will take great care when applying the harness and humeral cuff to ensure subject comfort.

FDA Status

Dr. Hidler, the PI of this study, has consulted with the FDA to determine whether an IDE is required for a class II medical device such as the exoskeleton. The policy of the FDA on device testing is that if the investigator does not believe the device presents a significant risk to subjects and the local IRB agrees with this assertion, then no IDE is necessary. MGAXOS may qualify for an automatic FDA premarket notification exemption as a class II medical device under CFR Section 890.1925 "Isokinetic testing and evaluation system" (<http://www.fda.gov/cdrh/modact/frclass2.html>). The InMotion2™ Robot (Interactive Motion, Inc., Cambridge, Mass.) is a commercial robot developed for stroke rehabilitation and falls under this classification. In addition, the MGAXOS has extensive embedded software and hardware safety features that are not normally incorporated in robotic devices such as the InMotion2.

Benefits

There is no direct benefit that will accrue to individuals participating in this study. Having arm exercise data to optimize the performance of MGAXOS is a critical piece of the development process. It is anticipated that once tested, MGAXOS will ultimately be used with patients with upper extremity impairments.

Subjects will not be paid to participate in the study.

L. ADVERSE EVENT REPORTING

Unanticipated problems involving risk to subjects or others, serious adverse events related to participation in the study, and all subject deaths should be promptly reported by telephone (301-619-2165), by e-mail (hsrrb@amedd.army.mil), or by facsimile (301-619-7803) to the U.S. Army Medical Research and Materiel Command's Human Subjects Research Review Board (HSRRB) as well as to the Office of Research Integrity at MRI. A complete written report should follow the initial contact. In addition to the methods above, the complete

written report may be mailed to the U.S. Army Medical Research and Materiel Command, ATTN: MCMR-ZB-P, 504 Scott Street, Fort Detrick, Maryland 21702-5012.

M. MODIFICATION/DEVIATION FROM PROTOCOL

Any deviation to the protocol that may have an effect on the safety or rights of the subject or the integrity of the study must be reported to the Medstar Research Institute IRB and to the USAMRMC ORP HRPO as soon as the deviation is identified.

Major modifications to the research protocol and any modifications that could potentially increase risk to subjects must be submitted to the USAMRMC ORP HRPO for approval prior to implementation. All other amendments will be submitted with the continuing review report to the USAMRMC ORP HRPO for acceptance.

No subjects will be tested until written approval is issued by Medstar Research Institute IRB and the USAMRMC ORP HRPO.

N. STUDY POPULATION – GENDER/ETHNIC INCLUSION

There will be no exclusion based on subject gender or ethnic background.

O. ADDITIONAL REGULATORY REPORTING REQUIREMENTS

The following are reporting requirements and responsibilities of the Principal Investigator to the United States Army Medical Research and Materiel Command's (USAMRMC) Office of Research Protections (ORP), Human Research Protection Office (HRPO).

(1) The protocol will be conducted in accordance with the protocol submitted to and approved by the USAMRMC ORP HRPO and will not be initiated until written notification of approval of the research project is issued by the USAMRMC ORP HRPO.

(2) Accurate and complete study records will be maintained and made available to representatives of the U.S. Army Medical Research and Materiel Command as a part of their responsibility to protect human subjects in research. Research records will be stored in a confidential manner so as to protect the confidentiality of subject information.

(3) A copy of the approved continuing review report and the local IRB approval notification will be submitted to the USAMRMC ORP HRPO as soon as these documents become available. A copy of the approved final study report and local IRB approval notification will be submitted to the USAMRMC ORP HRPO as soon as these documents become available.

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