A Visiting Associate Professor's Collaborative Research Experiences among Students, Faculty and Industry, for a Hand Opening Assistive Device (HOAD)

HOAD Research Group, P. I.
Edward M. Land: Appointed Faculty Member, Johns Hopkins University, School of Medicine

Visiting Associate Professor
Michael Marcus: Penn State University – York Campus

Student Research Assistants:
Aaron Abugaber, Rohit Dayal, Noah Greenbaum, Sally Hong, Jon hunt, Joseph Saltzman
Affiliation: Johns Hopkins University, Whiting School of Engineering – Homewood Campus

EDWARD M. LAND holds a faculty appointment at JHU, SOM as a Consulting Engineer, Principal Investigator and Instructor to PM&R, HOAD Research Group. Taught Advanced Assistive Device Technologies to BME, MechE, EE undergraduate and graduate students for 14 semesters. Serves as an invited judge, Whiting School of Engineering and SOM for CBID Medical Device Developments. Ed holds a BS from UMUC and 18Cr Hrs at the MS level at UMUC – College Park, MD Campus.

MICHAEL MARCUS is a Visiting Associate Professor, for Advanced Assistive Devices, in the Johns Hopkins School of Medicine. He worked in industry for 17 years in the Biomedical Instrumentation field as a Senior Project Engineer where he designed and submitted biomedical instrumentation to regulatory agencies. He is currently an Associate Engineering Professor at Penn State University - York Campus.

AARON ABUGABER is a Mechanical Engineering Senior at Johns Hopkins University. He is the senior most student Research Assistant member of the HOAD project, having worked on it since his freshman year. He is currently working on the CAD designs for the active device and is an integral part of the development and design of these components.

ROHIT DAYAL is a Senior in Biomedical Engineering & Applied Mathematics at Johns Hopkins University. He has devoted his time to determining the necessary steps required for the devices to meet FDA approval. Additionally, he developed an external Portfolio for HOAD that provides an overview to the general public which complements the two (2) US and two (2) foreign Patent Applications that were filed on July 7^{th} 2011.

NOAH GREENBAUM is a Junior in Biomedical Engineering & Electrical Engineering at Johns Hopkins University. His experience in electrical engineering has been a valuable asset from the onset of this summer 2011. Through his hard work, preliminary models of the Arduino circuit to be implemented in the active device have now become a reality.

SALLY HONG is a Sophomore in Biomedical Engineering at Johns Hopkins University. Sally has looked into the funding opportunities to sustain HOAD and its immense progress. She has researched extensively and assembled an informative Comparison Chart on competing hand-assistive products. Sally has identified 24 Predicate (or prior art) devices which have contributed significantly to the pool of hand assistive devices.

JON HUNT is a Sophomore in Biomedical Engineering at Johns Hopkins University. He joined the HOAD project this summer as a volunteer, but has played a pivotal role in converting all written materials from the past 6 years to a consistent electronic format. Jon has also identified a source of single breathable, wickable material whose outer layer is also hydrophobic. This fabric is needed to complete the shell of our medical glove.

JOSEPH SALTZMAN is a Senior in Mechanical Engineering at Johns Hopkins University. Over the past three years, he composed four research papers for the HOAD project team. The format of his term papers has become the standard for others to follow.

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Abstract

For the past year I have experienced working on a research project, as a Visiting Associate Professor, at the Johns Hopkins University, School of Medicine. This paper will describe the nature of my appointment, the course structure, personal contributions, how the project is documented using Dropbox, and the collaborative relationships within the university and industry, for a Hand Opening Assistive Device (HOAD) that is in its fourth year of development. This paper will describe the two types of HOAD medical devices under development and their intended use as rehabilitative appliances. In addition, the interaction of how graduate and undergraduate students have participated on this team over the semesters, taking the course for credit or as volunteers, to gain the experience of working on a team lead by an Engineer with many significant years of industrial experience. The steps in the project development will be described along with the contributions of various team members and how their work was evaluated. The regulatory aspects of this project will be described along with how an on-going search is made for competitive devices. Finally, the future direction for this project including: next generation developments, partnering with the Veterans Administration, other educational institutions, selecting manufacturing facilities and setting up future supply chain distribution will be presented.

1. Introduction (By Michael Marcus)
As an Associate Professor of Engineering at Pennsylvania State University, York Campus, I have worked with students on design projects for various courses that I teach. In addition, I have published in the area of teamwork that is based on my 17 years of experience as a Senior Project Engineer in Biomedical Instrumentation field.[1,2] As an instructor, I have program specific knowledge of how Capstone Projects work. As a researcher, I had little knowledge of how major Research Projects function that include Faculty, Undergraduate, Graduate Students, and their relationships with Industry. I had the opportunity this past year to collaborate with EDWARD M. LAND, the HOAD Research Project P. I. of the Hand Opening Assistive Device (HOAD) Research project from Johns Hopkins University.

Ed is a Consulting Engineer, for the Advanced Assistive Device Technologies Class that he teaches at the Johns Hopkins University, Whiting School of Engineering through a jointly sponsored agreement with their Biomedical Engineering Department. After describing my background, that included designing and submitting biomedical instrumentation to regulatory agencies, and my desire to become involved in the interesting project that he is heading, I offered my services to participate on his research effort. I submitted my Resume to the Advisory Board of the School of Medicine Faculty at JHU and was appointed as a Visiting Associate Professor, in the Department of Physical Medicine and Rehabilitation, Pro bono, working part time.

I will summarize my contributions to this program under the following topic areas: a) working with students to develop microprocessor software and driver electronics to control an active Hand Opening Assistive Device; b) working with students to determine which of the FDA guidelines and procedures would lead us to an FDA approval. c) Additionally, I worked with students on how to use a data acquisition system to obtain finger force measurements.

2. Research Area – HOAD Research Group. (By Edward Land)
Our unique, light weight and comfortable, low-profile hand-assistive 'glove-like device' is designed to serve as a rehabilitation, splint or exercise appliance. The device provides finger extension assistance for individuals who lack hand-extension ability as a result of stroke or other neurologic trauma, see Figure 1. Our research team has already developed a one-off, proof-of-concept, electrically powered, assistive device and has produced three mock-up versions of our passive (spring-assisted), hand-extension prototype. An articulating thumb assembly is currently under development for both passive and active styles. Each 'glove' is designed to be easily adjusted or modified to produce a 'best-fit' that is to be available in different sizes and customized to accommodate each client's precise needs while holding inventory to a minimum. Each glove-like device shall be capable of extending (or exercising) the closed fist of a particular class of stroke, accident victim or returning war fighter.

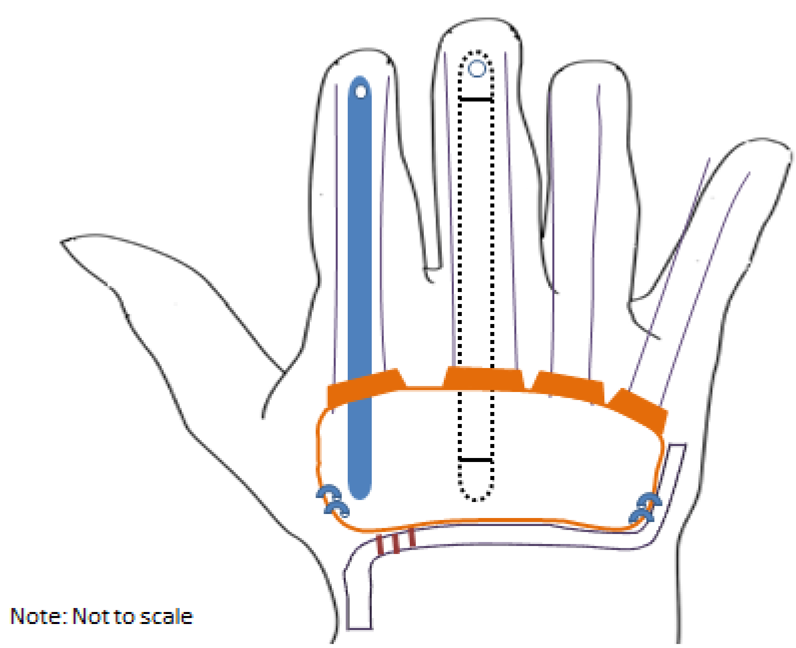

Figure 1. Top View of Actuator Blades into Glide Plate Stack

2.1 Project Team (By Edward Land)

Traditionally, we look for students who enjoy working with others in synergistic relationships. Each semester (for the past 14 semesters) we (HOAD Research Group) have actively recruited biomedical engineering (BME) student research assistants under a joint venture agreement with the Whiting School of Engineering (BME Dept) located at JHU's Homewood Campus. Two semesters after having established a successful BME track record, we began recruiting much needed mechanical engineering (MechE) RAs, and beginning summer semester 2011, electrical engineering (EE) candidates.

All research assistants (RAs) learn to perform basic and applied research and the importance of conducting peer reviews in order to benefit from lessons learned. HOAD Research recruits both volunteers and credit seeking students. The recruiting process is coordinated with the assistance of each department's engineering registrar and each student's advisor or sponsor. Classes for credit seeking students are capped at eight credit seeking students. Students report that they enjoy tracking down prior art (predicate) devices, discovering the potential benefits through testing and using new materials and processes during lab periods. Our team carefully evaluates leading edge device technologies, processes and competitive designs for consideration as our passive and active designs mature. New inductees learn from other RAs who in some cases, have been with HOAD for a number of semesters. Our ever changing core of seasoned RAs eagerly takes on the responsibility of offering their assistance to new students.

Additionally, a few students enjoy taking on stretch assignments such as: learning Computer Aided Design or being able to assist new RAs to learn about CAD design and rapid prototyping. Summer semester 2011, we had a total of eight students (four volunteers and four credit seeking) and for fall 2011 we have a total of eleven students, two of whom are seeking credit. We offer opportunities to earn up to three (3) credit hours. Unfortunately, undergraduate applicants are ineligible to receive compensation in lieu of credit.

2.2 Background and How Selected (By Edward Land)

HOAD Research Group was officially charted in August 2006 as a Johns Hopkins, School of Medicine (SOM), PM&R enterprise to develop affordable, low-profile, comfortable and light weight, hand extension, glove-like devices capable of opening the closed fist of a stroke victim or other person unable to open their affected hand. Co-inventors of the group consist of two engineers, three scientists and two physicians (see Acknowledgements). The heart and soul of our team is vested in the support we receive from an on-going, crop of JHU engineering student Research Assistants (RAs).

Figure 2. Passive Mockup, Side View w/Zipper

2.3 Condensed Course Syllabus [includes course structure] (By Edward Land)

Semester Requirements for all candidates [Classes run Tuesday evenings 6 to 8 PM]:

1. Prepare sketches and 3-D renderings of assemblies and sub-assemblies and save to Dropbox site.
2. Draft preliminary assembly instructions and conduct peer-review with assigned team members.
3. Establish and maintain working relationships with OEMs, suppliers and other Johns Hopkins University personnel.
4. Develop comprehensive understanding of: Rapid Prototype processes, memory metals, Peltier devices (TEC/TED), bi-metallics, EMG and temperature sensors, IMES type neural implants and wireless micro-controller communication devices.
5. Be willing and able to sew fabrics, assemble (or assist in the assembly of) references, summaries, findings, citations, presentations, grant applications, newsletters and press-releases; review same with instructor.

Internship(s): Prospective BME, ME, EE & 1st and 2nd yr Medical Student Research Assistants. Work assignments- Your team will develop a strategy, adopt a design, compare and contrast workable ideas through synergistic team collaborations working with 2-3 RAs (max). Your group shall include observations and findings, through the elimination of less robust designs in favor of simpler, more aggressive, and better suited ones. Selected students/RAs will be assigned to continuously review the on-going progress of competitive device designs and report their weekly progress/status to other classmates.

Graduate students or special students such as those receiving grants or stipends may also qualify as credit seeking. A 4-page, pre-approved*, research paper is required for all undergraduates (N/A for those seeking 1 credit hour). Graduate (first and second year) medical students who have pre-registered for multiple-semester assignments: a 15-20 page 'Journal Ready' primary research paper is required.

Research papers must focus and report on each, individually approved subject by providing a summery with a conclusion and most importantly, a recommended 'path-forward' (and reasons why). Sample research formats are available for review in our HOAD "Dropbox" for undergraduates. Graduate students are to follow any recognized 'physical science' journal such as Medical Device and Diagnostic Industry.

All RAs will need to plan for (and demonstrate) at least 40 total hours of dedicated work per semester to achieve consideration for each credit hour attempted.

Your performance will be evaluated on:

Computer Aided Design (CAD) renderings (requires peer review)	@15 – 20%
Class participation and relevancy	@15 – 20%
One general subject quiz [for new RAs only] (pre-announced)	@05 – 15%
Lab participation and project leadership/ project volunteerism	@15 – 25%
Research paper on a pre-approved topic* (related to our enterprise)	@25 – 30%
Weekly WEB informal research assignments (w/in-class presentations)	@10 – 20%

1 – 2 presentations per person, per semester to include:
- Grant submissions, HOAD planning, forecasting, updating;
- Managing activities; News releases/updates @ one per semester;
- Product, component, process & /or material assessments ~ two per wk.

Basic and Applied Research can be a lot of fun but your grade will cost you some time and dedication. Should you accept this challenge, please schedule your time accordingly. Our lab is open from 7 am until 5:30 on Tuesdays and on Thursdays from 7 am – 7 pm.

2.4 Student Participation (By Edward Land)

The students and faculty were given an interest inventory chart to complete shortly after formal class registration, in which they rank their level of interest and competence for various activities that will be needed by the project over the semester. They indicated the following on the chart: Their Proficiency, Interest, Willingness to learn, Willingness to teach, and if they were already working on it. At the conclusion, they assigned weighted values for each category listed. (See Table #1)

		Edward Land	Michael Marcus	Jon Hunt (V)	Noah Greenbaum	Rohit Dayal	Sally Hong (V)	Aaron Abugaber (V)
Clean up:	HOAD	I,T (1)		I3	I2	IP	I2	I
	Lab	P,T (1)			I3	IP	I2	I
Project Management:	Develop Milestone Event Schedule	IP,T (1)		I2,L		I2		
	Develop Parts Tree	I,T (1)						
	Implement Naming Convention	I,T (1)					I1	
	Procedure Development	IP,T (1)		I1				
Technical Skills:	CAD	I, L		I1,P2/3	P2	I1, L	I2, L	I1, P2
	3D Animation	I, L			P2	I1, L	L	
	Programming	I		I1,P1	P2			
	Photoshop	I				I1, L		
	Rapid Prototyping (Training Required)	I,L			P2, T		L	I1
Tech Research	Basic	IP,L (1)				IP		
	Applied	IP,L (1)		I2				
	Prior Art/Predicate Products	IP,L (1)				I2		
	Competitive Products	IP,T (1)	I2	I2		I2		
Materials	Research	IP,T (1)					P2	
	Selection	IP,T (1)						
	Testing	I,T		I1			I2	
Next Gen Tech	Electroactive Polymers	I,L						
	TED/Peltier Devices	I,L	I2		I2, P2			
	Piezoelectric Devices	I,L		I2,L				
	Micro Linear Actuators	I,L	I2,P2	I2				
Passive Device		I,T	I2					
Active Device	Bushing	I,T (1)						I1
	Heating Elements	I,L	I2					
	Housing Manifold	I,T (1)						I2
	Electrical Components	I,L	I1,P2,T2					
	Microprocessor	I,L	I1,P2,T2	I1,P1				
	Wireless Communication				I1, P2			
	Sensors and Controls	I,L	I1,P2,T2	I1				
	Battery Selection and Charging	I,L	I2					I2, P2
Prototypes	Finish Mock-up	IP,T (1)				I3		
	Develop Passive Device Prototype	IP,T						
Lab Testing Development	Finger Force Data Collection (Labview)	I,L	I1,P2,T2	I1,L			I2	
	Strain Gauge Force Mechanism	I,L	I2	I1,L			I2	
Establish Collaborations		IP,T (1)						
Patient Recruitment		I,L						
Presentations		IP,L (1)	I1					
Grant Work	Solicit funding	IP,T	I2			I2,L	I2,	
	Write up applications	IP,L (1)	I2			I2,L	I2,P3	
	File applications	IP,L (1)					I2	
Patent	Research	IP,T (1)					I1	
	Filing	IP,T (1)					I1	
FDA Protocol Testing		I,T	I1,P2,T2			I2,IP		
Multilingual	[Fill in Languages]							
	Spanish					P3	P3	
	German							
	Chinese							
	Korean						P1	
Legend:	Hindi					P1		
Proficient	P							
Interested	I							
Willing to Learn	L							
Willing to Teach	T							
In Process (Already Working on it)	IP							
Level	1 [High], 2 [Medium], 3 [Low]							

Table 1. Faculty and Student Interest Inventory Sheet

3. Work performed by HOAD student Research Assistants

3.1 Description of the two hand-assistive devices (By Noah Greenbaum)

The Hand-Opening Assistive Device from HOAD Research is a glove that contains special (purpose-built) hardware to allow a patient with compromised hand functionality to open that hand. There are two versions in development; an unpowered ("passive"), "spring assisted" version, and a powered ("active"), "computer controlled" version. While both passive and active devices are related in form and function, they serve two distinct purposes. The passive device has a lower overall cost and complexity (Fig . 2) . It may be adapted for a majority of stroke, accident and injury cases. It is best suited for most applications involving neurological trauma to the head, neck, elbow, arm and hand resulting in a dysfunctional hand. The highly customized, active device, however, has much tighter specifications, allowing for volitional control of individual fingers of the hand and discrete feedback to the computer (Fig. 3). Note: Active Nitinol (NiTi) driven-hand HOAD orthotics must be operated in a controlled (enclosed) environment such as the home or office. These devices are typically custom programmed to operate optimally, indoors unless otherwise specified.

The passive device is entirely mechanical. Straight strips of a super-elastic NITi material are elevated just above the fingers, and the force generated by each strip is sufficient to overcome the patient's deficit. The patient is able to override the material by applying a controlled counterforce, permitting the patient to modulate their hand function with their own grip control. The lifting actuator strips are integrated into channels in the glove to prevent lateral slippage and minimize the (low profile) height of the device to about one-half inch. The blades are anchored just above the finger tips and travel above the knuckles, terminating above the hand, where a stack of PTFE-coated fiberglass blades constrain their vertical movement and allow for finger splay without blade clash. Easy access to the blades and the stack is provided via a zipper that is later "stop-stitch" sewn to prevent unintended access. The wrist is mobilized in a similar manner as the fingers, but the blades enter the stack from the reverse side. For the thumb, cylindrical rods of the same super-elastic NiTi are constrained in nylon channels, which provide the same restorative force without overly restricting the natural range of motion of the thumb.

The active device allows for fine control of the compensation for the patient's deficit, as well as being an "on-demand" device rather than applying constant force. This on-demand force is exerted on each finger individually by a NiTi strip that has been shape set "annealed" in a flattened form, mimicking a finger's full extension. The patient has the ability to close their hand as normal, as the NiTi is malleable below transition temperatures. When the NiTi is heated, it returns to its shape-set annealed form. This provides an even and powerful force across the entire finger, and in concert with the other fingers, opens the hand.

In a clinical setting, the passive and active devices overlap in function and potential application. The passive device requires lower labor and cost to produce, assemble, and maintain, as the materials are chosen for strength and durability characteristics and require no batteries to operate. It can be used in a controlled setting for rehabilitation therapy, or for extended use in an outpatient setting. The active device is more expensive, but offers increased control, creating a more versatile device. In addition to inpatient and outpatient therapy, the device would be appropriate for patients with permanent deficits, restoring function to an otherwise minimally useful hand. In addition, the granular control can restore function to single fingers or joints, correcting a wider range of deficits than the passive device.

Figure 3. Passive Mockup, Top, Interior View

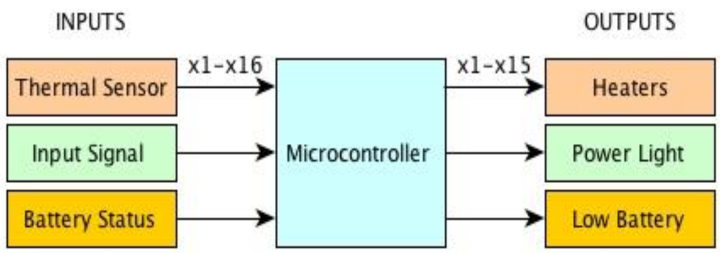

Figure 4. Block Diagram of Active Device showing Control Circuitry

3.2 How Documented (By Joseph Saltzman)

Every element of each student's contribution to research is maintained interactively such that member students or faculty are able to review the latest version and with permission, are allowed to peer review/edit any file of interest. In this manner, anything stored in HOAD Research Group "Dropbox" is the latest rendition. Users may also elect to restore earlier versions should that become necessary. Below is a sample of this format:

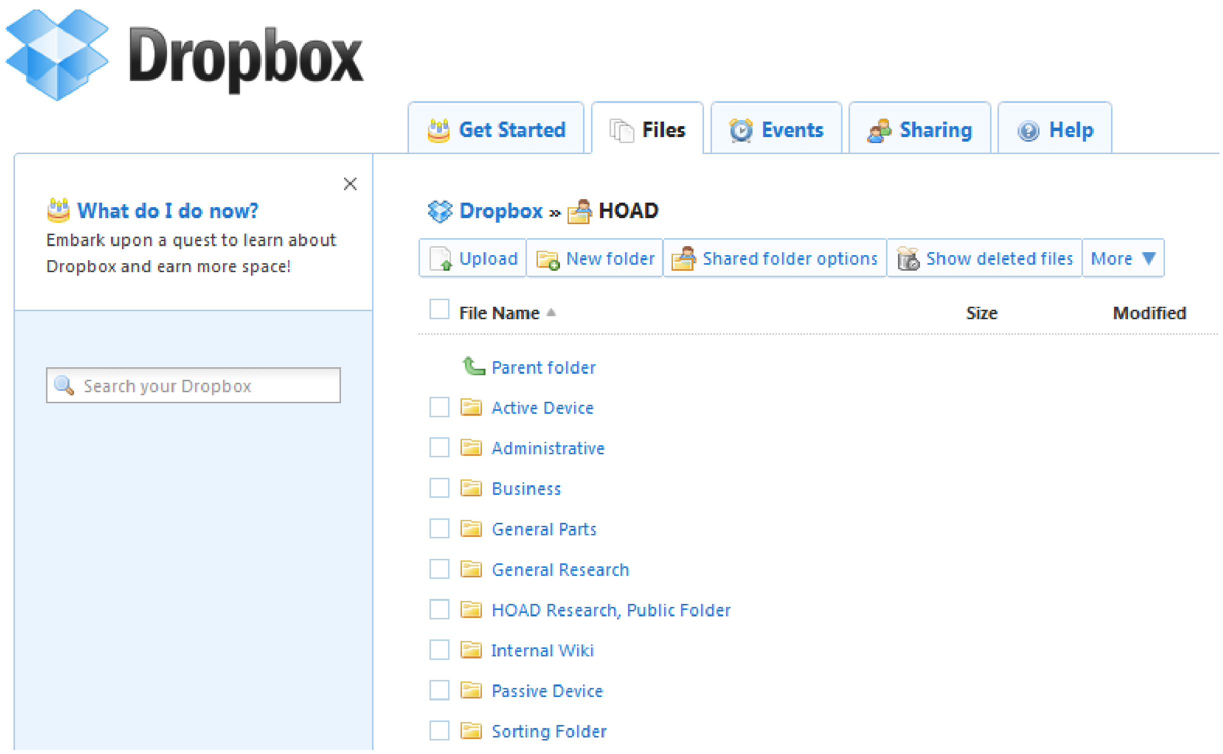

Figure 5. Generic "Dropbox" Web Site Offering

3.3 Force Testing and Measurements (By Noah Greenbaum)

As a prerequisite for customizing a HOAD glove-like device for a client, a doctor or clinician must measure the severity of the client's hand-opening or closing deficit for each affected finger or other medical trauma that may qualify them as a suitable candidate to use either of the HOAD hand orthotic devices. Patient dysfunction and severity measurements must be collected in order to pre-qualify them and to determine the counter-force actuator blade(s) best suited for that particular patient. HOAD Research Group is developing a method to measure the finger strength deficit for each individual finger. The client would utilize an electronic force measurement instrument and apply his or her maximum finger extension force against the instrument, producing a measurable voltage within the force measurement device, and would repeat the process for each finger of the affected hand. This force measuring instrument would be connected to an input channel of National Instrument's data acquisition hardware, allowing the data to be transferred to a connected computer running LabVIEW, a GUI-based programming environment. Using a coding structure our research assistants are developing, the LabVIEW program which will collect the force voltage data of each finger, calculate the force associated with the voltage data, and output a data table conveying the client's extension force for each individual trial and the deviation of the client's extension force from the norm. Obtaining this data, the doctor or clinician may determine the type and number of NiTi blades that should be installed into each specific actuator blade channel of the HOAD glove to match the client's individual needs, thereby optimizing the HOAD glove's effectiveness for each individual patient.

3.4 Searching for competitive devices (By Sally Hong)

On-going searches for competitive devices are performed. The table below is an “Excel” extract.

Company	MSRP [$ USD]	Active/ Passive	Commercial or R&D	Use	Ease of dress (don/doff)	Light weight	Low profile	Range of Motion	Wrist position	Comfortable	Weather Resistant
#1	7908	A	C	Full	Y	Y	Y	Y	None	Yes	N/A
#2	38	P	C	Full	N	Y	Y	None	Fixed	Yes	Yes
#3	305 (base)	P	C	Full	Y	Y	Y	N/A	None	Yes	Yes
#4	240	P	C	Supervised	Y	Y	Y	Partial	None	Yes	Yes
#5	1000	A	R&D	Supervised	N	N	N	Partial	Fixed	N/A	N/A
#6	1000	P	C	Supervised	Y	Y	Y	N/A	N/A	Yes	N/A
#7	1690	P	C	Supervised	N	N	N	N	Fixed	No	Yes
#8	119	P	C	Full	Y	Y	Y	None	None	Yes	Yes
#9	N/A	A	R&D	Supervised	Y	Y	Y	Full	None	Yes	No
#10	40	P	C								
#11	N/A	A	R&D	Supervised	N/A	N/A	Y	Partial	None	N/A	No
#12	not on market	A	R&D	Supervised	N/A	N	Y	Partial	None	Yes	No
#13	117	A	R&D	Supervised	N/A	Y	Y	Partial	Fixed	Yes	No
↓					↓						↓
#23	not on market	No	R&D	Full	Y	Y	Y	Partial	None	No	Yes
JHU HOAD	Competitive	A,P	R&D	Full	Y	Y	Y	Full	Full	Yes	Yes

Table 2. Competitive/ Predicate Devices [sample extract]

3.5 Meeting FDA regulatory requirements (By Rohit Dayal)

FDA Medical Device Approval Process for HOAD Research Unpowered and Powered Glove-like Devices (an overview)

Navigating the FDA process for a medical device is difficult, no matter the kind of device. Depending on the complexity and safety issues of the device, the approvals process can stall, move through several convoluted steps, and possibly even revert to previous steps. Fortunately, there are classes and lecture series dedicated to explaining these intricate steps to developers. The HOAD Research team broadened their knowledge base on the FDA process at a (XXX) FDA lecture series taught by visiting professors who currently work at the FDA.

The “take-aways” from the class, talks with FDA officials, and other medical device companies for the HOAD Research team enables us to navigate the process effectively and determine that both devices can reference predicate devices currently on the market to establish them both as Class I devices. One can find predicate devices on the FDA website and is an immensely useful resource for any device developer - no matter how big or small. The site is as follow: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm

The following are steps of the FDA process: (1) Investigational Device Exemption for preclinical trials, (2) Premarket Program Submission to determine its risk classification, (3) Design Controls to ensure device design conforms to end-user specifications, and (4) Post-market Surveillance Program to check device safety after FDA approval.

HOAD Research will have to devise a clinical testing program for its two devices to show them as substantially equivalent to predicate devices currently on the market. After this is established, the HOAD devices can clear a 510(k) premarket notification since it is substantially equivalent to a predicate device and avoids significant costs and time to process since a similar device has already been approved. The HOAD devices will likely spend less than the average amount of time in the FDA device process because it has evidence of being "substantially equivalent". This could not have been done without significant research on the FDA website and the informative FDA lecture series hosted by Johns Hopkins - both extremely valuable teaching tools.

3.6 Other Regulatory Agencies (By Michael Marcus)

During my industry tenure, I submitted Hematology Analysis Equipment to various regulatory agencies. The FDA Class of equipment was clearly defined and the path to take with the FDA was already established with other similar (predicate) devices within the company. However, the path to take with the FDA for these Hand-Opening Assistive Devices was a unique challenge. After attending the FDA in-house, lecture series at Johns Hopkins, School of Medicine, and a workshop from Medical Design and Manufacturing (MD&M), I gained more knowledge of the requirements for these devices and how to receive up-to-date, FDA information related to medical devices.

Since the Active HOAD appliance includes electronic circuitry, one other area that we will look into is to apply for the equivalent of an Underwriters Laboratory (UL) listing, but use a harmonized standard IEC 60601-1, which also covers other countries. Additionally, we may seek a specialized marking for Medical Equipment for the European Union (CE Marking) when the devices are to be sold through licensees in Europe.[3]

3.7 HOAD Student Self-Evaluation (By Edward Land)

Student: ________________ Advisor: ________________ BME, MechE, or EE: ______
Evaluation date: _____ Your email: _____________ Other participating team members:
____

Instructions: The following self-assessment is to be completed via email; you have seven days. Identify all response entries by the item number shown below.

Notes: A. Grade yourself using 1 as "BEST performance", on a five scale.
B. Ensure that you include this page with your email response.

Basic precepts: Participating RA students are graded on their…

1. Active lab/ class-room participation [You must attend regularly.] —
2. Team leadership [planning, peer review teams, needs assessment & futures forecasting] —
3. Demonstrated technical competence and growth—
4. Quality of completed assignments —
5. Volunteerism [weekly assignments, parts lists, product research, news letter updates]—
6. Weekly time-tracking [a bona fide requirement, in-lab @ 6 – 9 hours/wk] —
7. Comprehensiveness of work—
8. Depth of knowledge and understanding of particular subject matter [including quiz results] —
9. Relevant use and application of technical terms in the area of:
   - Your term paper—
   - Biomechanics—

- MS suite of products [and computers in general] —
- CAD renderings [quality & completeness] —
- Material & component assessments—
- Process improvement & lessons learned—
- Mechanics, manufacturing, assembly, physics—

Footnote: "Students must provide examples for each response offered (See above 1 - 9)."

4.0 The Project Development Research Process (By Edward Land)
4.1 Steps in Project Development, [Process Flow Chart]
Define the problem> map out viable solutions> survey materials & methods> determine affordable option (time, materials, facilities & technologies)> develop preliminary sketches> review competitive devices (regularly)> assemble detailed sketches & CAD renderings> conduct internal peer review> review plan for soundness> conduct extensive "what if" evaluations> develop proof-of-concept> sell idea to management> acquire access to labor, facilities & test equipment> focus efforts to build collaborative team> recruit support network> recruit/maintain research assistants> draft provisional patent[6,7] application> request material donations for testing> develop mockup device> evaluate student performance> assign grades> establish collaborative relationships with internal technology transfer department> file patent application(s)> roll lessons learned into mockup> construct 1st generation prototype> invite OEMs & Financial Angles to review progress> establish collaborative relationship with Veterans Administration, local businesses and other educational institutions> evaluate "doable" internal & external grant applications> develop one-year realistic grant opportunities> review opportunities with collaborators> develop internal & external Milestone Event Schedules> assemble MES timeline with team of assigned student RAs> identify all required cost elements> compose a budget w/justifications> file targeted grant applications (do not overreach)> locate suitable venues to publish research efforts> select only one publisher for each writing effort> develop documentation suitable for publishing> concurrently meet all monthly grant expectations> apply for follow-on grant monies> down select manufacturing facilities> license technologies and IP for university> OEMs must have access to supply chain/distribution system> transition licensed technology to full service OEMs.

4.2 Value Stream Map

Divide usher glove into 2 ⇨ Assemble glide plate stack, blades and padding onto the top piece of glove ⇨ Secure blades near fingertips: rivet blades to glove/ Lanyard cross/lanyard strap/thread – sew in hole ⇨

Sew blade

⇨ Add gusset (the piece of fabric sewn between the fingers on glove a.k.a. sidewall or fourchette; each section of material to be in a differently colored, non stretchy material from usher glove material) ⇨ Add Zipper pouch ⇨ Use Velcro straps to comfortably secure glide plate stack to glove body. Ensure that Hook Strap is narrower than Loop strap to prevent exposed Velcro Hooks from damaging clothing.

4.3 RA Rules to Live By [Issued to all students]

- Your class attendance is mandatory.
- You must be willing and able to perform lab duties and record your time.
- Volunteers are not required to submit a 4 page (min) research term paper but your submission is encouraged (its good exercise).
- You must be passionate about learning and contributing.
- You must demonstrate ability to improve Mechanical & CAD rendering skill sets.
- First timers are required to take and pass a twenty-question, pre-announced quiz.
- You must be willing and able to synergistically work on 2 or 3 person teams and make yourself available to do so.
- You must be willing and able to timely conduct assigned research activities and communicate your findings to your instructor.
- You must respond to your instructor's inquires (its mandatory).
- You must deliver the goods on time every time; your commitment is your bond.

4.4 Benefiting from the University Library System (By Edward Land)

NOTE: When conducting your research from any university library system, substitute your particular engineering discipline for the term "medical".

- Use "Google Scholar" when searching for either very detailed information or broad, multidisciplinary info. Scholar gives mostly journal article citations. Use Google as a last resort and with phrases in quotation marks to narrow your search as much as possible.
- From a research perspective, we are concerned with 'granularity'; the process of reducing our search down to the level of detail where most of the answers we seek may be found.
- Useful "medical" data bases and web sites to examine: CDC; Pub Med; Institutes; Fast Stats: National Center for Health Statistics; market research.com/academic; RefUSA; Medical Device Register; Space Modern- BME Devices; Community of Science; Chronicles of Higher Education and the Hanger Orthopedic Group.
- When looking for patient reimbursements to offset the cost of purchasing our device(s) examine applicable Center for Disease Control and Prevention (CDC) codes, collaborate with the Veterans Association to recruit their patients and establish a medical necessity on their letterhead.
- Under Pub Med, carefully examine the 'first paragraph' and not the abstract to see if the information you seek is available in the document.

- Under Institutes, look for ‘neuro’ and stroke to locate related organizations.
- Cross referencing tools: Review engineering- BME- FDA- regulations- CFR- CDC- Traumatic Brain Injury (TBI) topics.
- RefUSA has dollar amounts listed by product.
- Medical Device Register is a ‘print-only’ publication that is available in two volumes. One volume, lists manufacturers while the other is sorted by key words. These may not be checked out of the library!
- www.oandp.com/articles/news_2007-09-28_01.asp Prosthetics Market Growing
- www.aopanet.org American Orthotic & Prosthetic Association
- www.hanger.com Hanger Orthopedic Group – Prosthetics, Orthotics, Artificial Limbs, …
- When using the JHU Sheridan Libraries as a research tool it is important that you start with their ‘Advanced Level’ search function and drill down from there.
- Examine GRAY SHEET and click on the heading ‘more options,” and then check the boxes for GRAY SHEET and the one right underneath, “Health News Daily,” because those are the only ones that we own.
- In PubMed, (1) always go through the library web site to PubMed, and DON’T use “pubmed.gov.” The reason is that we have our full text linked to PubMed but you won’t get it if you use the generic URL. (2) In PubMed, Look at the bottom under MeSH (Medical Subject Heading). This is the world’s best thesaurus and will be great at helping you narrow down what you’re hunting for.
- Other library reference materials are also available in the lab for your review. We have hand-outs on the following subjects: National Institute of Neurological Disorders and Stroke (sub categories include definitions, treatment, prognosis, current research and patient recruitment for clinical trials); Traumatic Brain Injury (sub-categories include distribution by age, State, cost, outcomes, gender, population, risk, prevention and treatment.
- Collexis is a Hopkins internal database document that contains published works of BME experts, taken only from PubMed. If however, other scientists and researchers have not yet published; their efforts and contributions will remain unknown to the outside world. This no doubt, also applies to all institutes of higher learning. The message to take home is that you will never know for sure what competitive research is underway unless you physically pick up the phone and ask.

5. HOAD Devices

5.1 Intended use (By Edward Land)

Over a million stroke victims in the US alone (1) are unable to open their affected hand. Yet, a portion of these individuals, estimated to be 220,000, retain their ability to volitionally control their arm and their hand grip strength. Our charter is to develop comfortable, low profile and robust hand-assistive glove-like devices which enable the wearer to reopen their affected hand.

The successful completion of each of these devises has strong national and global implications to the patient and to the marketplace.

Figure 6. Passive Mockup Device, with Zipper Access, Side View

A total of four (4) US and foreign patents are pending (July 7th 2011) for two passive (spring assisted) and three active (computer controlled) hand-orthotic devices. For individuals who have retained their grip and their ability to direct their arm movements, but not the ability to open their hand, each customizable device will offer the stroke, traumatic brain injury (TBI) or ulna nerve patient a counterforce sufficient to extend the user's hand by overcoming grip strength and improper wrist positioning.

6. Collaboration with Business and Industry (By Edward Land)
Extensive collaborative relationships have developed over the past five years in support of our assistive device charter. Under a joint venture agreement among JHMI School of Medicine, PM&R Department the BME, MechE and Electrical Engineering Departments at JHU Homewood campus our team is fortified each semester, with undergraduate and graduate research assistants.

We already have in place, a letter of understanding that 1st and 2nd year medical students are invited to participate in a pilot study or clinical trials as our research matures and the need arises for clinical trials. Over this same period, we have had access to the use of rapid prototyping machines being offered by a local, Baltimore firm, PCS; material donations from: BSST include a working Peltier (thermoelectric device); Northrop Grumman Corporation include a $2200 KEPCO power supply; Signode Corporation including a plant tour, banding straps, tools, clamps; Johnson Matthey and Fort Wayne Metals Corporations including expensive NITINOL material samples; Ansell Health Care Products, located in SC (military glove division), have provided about thirty (30) pairs of sample gloves provided to HOAD Research Group. Additionally, we have located a glove designer source at Clemson University (Clemson Apparel

Research) a strong glove design subcontractor. Alternatively, we have located as a back-up plan, Carolina Glove and Safety Company located in Conover, NC.

7. Future Direction (By Edward Land)

At this time we are in the process of updating a third generation, passive, spring loaded, glove-like, assistive device prototype test fixture. Our first three mock-ups did not contain provisions for an articulating thumb, nor physical Nitinol (NiTi) actuator lifting elements while the fourth version will be designed to include these capabilities. These super-elastic (Ni Ti), stainless steel or fiber impregnated counterforce actuator elements are designed to permit a patient's full hand to open easily, (assuming that the patient already possesses the ability to extend and splay their fingers). We are constantly on the lookout for qualifying grant opportunities. Soon, we will be developing two grant proposals; one is internal JHU ATIP, the other is for the State of MD through TEDCO. FYI, Our internal Hopkins ATIP grant proposal opportunity occurs every six (6) months.

8. Next generation development (By Edward Land)

It is important to note that over the past five (5) years, this enterprise, save for corporate contributions previously mentioned, was developed exclusively by volunteers. Credit seeking and volunteer students have basically paid the university to participate in our program and their contributions have been noteworthy in that they, as research assistants, are required to produce term papers that after faculty edits are worthy of study by other students who also support this program as new volunteer researchers.

As hardware designs have matured, internal entities such as JHU Technology Transfer and outside organizations like Clemson University and MYOMO are beginning to take note. As mentioned earlier, we have successfully filed patent applications which provide us with a better understanding of the implications and technologies that will be needed to refine our device ideas. A better understanding will also enable us to affordably offer these refined devices to those in need and perhaps offer them a better quality of life in the process.

We also realize that, we must now infuse real monies from grant capable sources to continue to drive this to fruition. Grant monies will permit us to complete our efforts to have working devices suitable for testing and evaluation, case studies, pilot program development and clinical trials. Additionally, it has become increasingly clear that our active (computer controlled) hand-orthosis models, may have other useful implications in the development of assistive devices for other body parts or as a scale-to-need, light weight, alternative to heavy motor driven robotic tools.

9. Conclusion (Visiting Michael Marcus and Edward Land)

As a result of my joining the HOAD Research project team, I now have a road map of how a major collaborative Research Project functions involving Faculty, Undergraduate, Graduate Students, and how to gain support within the University and from industry. I learned how to structure a course to interest undergraduate and graduate students who take the course for credit, and as volunteers. Students learn individual elements and all phases of research and product development, which make them more knowledgeable as Researchers and Engineers and therefore more attractive to academia or industry upon graduation. I was encouraged to see how students eagerly participated in brain storming sessions, led by the Edward Land the Director of the Hand Opening Assistive Device Project. Ed taught and mentored participants to work synergistically and drive HOAD Research to fruition by establishing a plan-forward, and never without a Plan-B as an alternate solution. From an interactive Milestone Event Schedule, students were encouraged to select an area of interest that best suited them. In this way students are able to accept leadership roles or work with their instructors and other students who were willing to learn as the group conducting research or worked on CAD renderings etc. Students who had previously expressed an interest in a particular subject were asked to make direct contributions in those areas; some of their work is also included in this paper. As these two hand rehabilitative devices progress, it is our intention that these devices advance in sophistication permitting them to achieve their intended goal of enabling people with hand disabilities improve their quality of life.

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